(b) (4) Report No. 38166
Amendment No. 1 to Final Report

(b) (4)

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

(Final Report dated 01 July 2020)

Sponsor:
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17 September 2020

This Amendment No. 1 to Final Report consists of 2233 pages and 4 pages.
This is page I.

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REASONS FOR AMENDMENT NO. 1 TO FINAL REPORT

Upon request of the Sponsor, minor layout changes and/or corrections are made to the report that do not affect the validity and scientific results or the conclusions of the final report.

The following changes were made:

1. SUMMARY - FINDINGS

To improve readability and provide a more comprehensive summary, all Text tables are deleted from Section 1.2 and replaced with references to the respective Text tables in the results section of the report.

Furthermore, in Section 1.2 in the paragraph on local tolerance the finding of eschar formation was incorrectly described with occurrence on test days 14 and 15 instead of on test day 14 only. Additionally, in the paragraph on haematology and coagulation the finding of an increased number of eosinophils in groups 4, 5 and 7 was missing. Further, in the paragraph on clinical chemistry the directions of changes for albumin and globulin levels were incorrectly stated as an increase in albumin and a decrease in globulin plasma levels instead of a decrease in albumin and an increase in globulin plasma levels.

In this Amendment No. 1 to Final Report the incorrect finding of eschar formation and the incorrect directions of changes for albumin and globulin are corrected, and the finding of an increased number of eosinophils in groups 4, 5 and 7 is added.

2. TEST ITEM

In Section 2.3.5 on test item no. 5, the designation for the test item was incorrectly given as ‘modRNA’ instead of ‘saRNA’.

In this Amendment No. 1 to Final Report the incorrect designation is corrected.

3. RESULTS

In Section 4.7 the finding of an increased number of eosinophils in groups 4, 5 and 7 was missing. Additionally, in Section 4.8 the directions of change for albumin and globulin levels were incorrectly stated as an increase in albumin and a decrease in globulin plasma levels instead of a decrease in albumin and an increase in globulin plasma levels.

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In this Amendment No. 1 to Final Report the incorrect directions of changes for albumin and globulin are corrected, and the finding of an increased number of eosinophils in groups 4, 5 and 7 is added.

4. TABLES

In Table 1 2 (Local Tolerance Erythema, Oedema, Induration, Hardening) the incorrect test item 'BNT162b1' instead of 'BNT162a1' was stated for Group 3. In addition, the grading scale as given in the footnote was specific for erythema only, and the gradings for oedema and indurations were missing.

In this Amendment No. 1 to Final Report the incorrect test item is corrected. The grading scale given in the footnote is referred to erythema, and additionally, for oedema and indurations the respective grading scales are given as a reference to Section 3.8.3.

5. ADDITIONAL CHANGES

In Section 4. 1, the main sentence of the last sentence of the second paragraph was missing the verb "was noted", which is now added to the text (i.e. "[...] was noted on test day 14 [...]").

The following typing errors in the Final Report are corrected by this Amendment No. 1 to Final Report:

Quality Assurance Statement: Year of the Study Plan '16 March 2020' instead of '16 March 2019'.

Section 4. 7: In Text table 4 9, for the parameter "eosinophils" the sex is corrected from 'm' to 'f'.

Section 4.8: In Text table 4 12, for the parameter "globulin" the entry 'Group: 4, Sex: m, Test day: 17, Change: + 9.5% * *' is corrected to 'Group: 4, Sex: f, Test day: 4, Change: +9.5% *'.

This amendment does not affect the validity of the data.

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This Amendment No. 1 to Final Report has been audited by the Quality Assurance Unit (QAU) and is considered to be an accurate account of the project.

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(b) (4) Report No. 38166

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Sponsor:
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STATEMENT OF COMPLIANCE

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

The study was performed in compliance with:

- 'Good Laboratory Practice' Regulations of the EC enacted in Germany in the 'Chemikaliengesetz' [Chemicals Act], current edition;
- 'OECD Principles of Good Laboratory Practice' Document No. 1 (ENV/MC/CHEM (98) 17) regulated in the Directive 2004/10/EC of the European Parliament and the Council of 11 February 2004.

These principles are compatible with 'Good Laboratory Practice' (GLP) regulations specified by regulatory authorities throughout the European Community, the United States (EPA and FDA) and Japan (MHLW, MAFF, and METI). Animal husbandry is performed in compliance with EU Welfare Standards (Directive 2010/63/EU).

Raw data obtained during the performance of the study are accurately reflected.

The analysis of dose exposure was conducted under the responsibility of the Sponsor and is excluded from this statement.

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QUALITY ASSURANCE STATEMENT

Based on a quality assurance review, it was concluded that this report accurately reflects the raw data for the study. Methods, procedures and observations are correctly and completely described in the report:

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

Study Plan dated 16 March 2020 and 9 Study Plan amendments.

Text table 1: Inspections of (b) (4) QAU

Date of inspection	Criteria	Date of report to the Study Director and the Management
16 Mar 2020	Study Plan.	16 Mar 2020
17 Mar 2020	Sponsor's visit: Prearrangements for test item preparation, administration, body temperature, local tolerance, documentation.	17 Mar 2020
24 Mar 2020	Body weight, blood withdrawal and processing for cytokine determination, time points of blood withdrawal, labels, administration, body temperature, local tolerance, documentation.	24 Mar 2020
31 Mar 2020	Blood withdrawal and processing for cytokine determination, time points of blood withdrawal, labels, administration, body temperature, local tolerance, documentation.	31 Mar 2020
08 Apr 2020	Urine collection, blood withdrawal and processing for laboratory examinations and for dose exposure analysis, dissection, organ removal, organ weights, documentation.	08 Apr 2020
21 Apr 2020	Body temperature, administration, blood withdrawal and processing, kinetics, labels, local tolerance, documentation.	21 Apr 2020
23 Apr 2020	Blood withdrawal and processing for laboratory examinations, dose exposure analysis and cytokine analysis, animal sacrifice, dissection, organ removal, organ weights, bone marrow smears, documentation.	23 Apr 2020
26 June and 29 June to 01 July 2020	Final Report.	01 July 2020
15 and 17 Sep 2020	Amendment to Final Report.	17 Sep 2020

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In addition to the detailed study-based inspections, series of routine facility inspections were also conducted and reported to the Management.

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EXPLANATIONS AND ABBREVIATIONS

Symbols

[1 - n]	reference to footnotes in text
#(n)	reference to footnotes in text tables
( )	animal number in the tables section
%	per cent
!	refer to result comment at the end of the table
…n	inappropriate for statistics (number of individual data values is less than 3 or all values were below lowest level of quantification, e.g. for cytokines)
↑	increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls
↓	decrease relative to study control range, but % difference not quantifiable due to lacking concurrent controls

Letters and acronyms

% Diff	percent difference (from control group)
a.m.	ante meridiem
abs.	absolute
ANOVA	analysis of variance
approx.	approximately
b.w.	body weight
EC	European Commission
EPA	Environmental Protection Agency (USA)
EU	European Union
f	female
FDA	Food and Drug Administration (USA)
GLP	Good Laboratory Practice
i.e.	id est (that is)
i.m.	intramuscular
Inj.	injection
LLOQ	lower limit of quantification
LNP	lipid nanoparticles
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m	male
MAFF	Ministry of Agriculture, Forestry and Fisheries (Japan)
METI	Ministry of Economy, Trade and Industry (Japan)
MHLW	Ministry of Health, Labour and Welfare (Japan)
MS	main study
n, N	number (e.g. group size, sample size)
n/a	not applicable
ns	not statistically significant
OECD	Organization for Economic Co-Operation and Development
p.a.	post administration
p.m.	post meridiem
PBS	phosphate-buffered saline
PEG	polyethylene glycol
PrDs	predose

- Letters and acronyms continued on the next page -

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Letters and acronyms *(continued)*

QAU	Quality Assurance Unit
RBD	receptor-binding domain
rel.	relative
RNA	ribonucleic acid
mRNA	messenger RNA
uRNA	uridine mRNA
modRNA	nucleoside-modified mRNA
saRNA	self-amplifying mRNA
RP	recovery period
SA	satellite animals
SARS	severe acute respiratory syndrome
SARS-CoV	SARS coronavirus
SD	standard deviation
SOP	Standard Operating Procedure
TD	test day
TS	terminal sacrifice
TW	test week
USA	United States of America

Weights and measures

°C	degree Celsius
cm	centimetre
dL	decilitre
fL	femtolitre
fmol	femtomole
g	gram
h	hour
kg	kilogram
L	litre
mg	milligram
min	minute
µg	microgram
µL	microlitre
µmol	micromole
mL	millilitre
mm	millimetre
mmol	millimole
sec	second
U	unit

Measuring units

Body weight in g
Food intake in g/kg b.w./day
Absolute organ weights in g
Relative organ weights in g/kg b.w.
Relative urine volume in mL/kg b.w./24 h

Haematology / Coagulation

aPTT	activated partial thromboplastin time
Baso	basophilic granulocytes

- Haematology / Coagulation continued on the next page -

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Haematology / Coagulation *(continued)*

Eos	eosinophilic granulocytes
HCT	haematocrit
HGB	haemoglobin
LUC	large unclassified cells
Lym	lymphocytes
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
Mono	monocytes
MPC	mean platelet component
MPV	mean platelet (thrombocyte) volume
Neut	neutrophilic granulocytes
PDW	platelet distribution width
PLT	platelets
PT	prothrombin time
RBC	red blood cell count (= erythrocytes)
RDW	red cell distribution width
Reti	reticulocytes
WBC	white blood cell count (= leucocytes)

Clinical chemistry

Alb.	albumin
ALAT	alanine aminotransferase
aP	alkaline phosphatase
ASAT	aspartate aminotransferase
CK	creatine kinase
Glob.	globulin
Gamma-GT	gamma-glutamyltransferase
LDH	lactate dehydrogenase

Cytokines

IFN-gamma	interferon-alpha
IL-1beta	interleukin-1 beta
IL-6	interleukin-6
IL-10	interleukin-10
TNF-alpha	tumour necrosis factor-alpha

Urinalysis

+	'small amount' of analyte/few in some fields examined
+ +	'moderate amount' of analyte/few in all fields examined
+ + +	'large amount' of analyte/many in all fields examined
ery	erythrocyte
LC	lemon-coloured
neg	negative/none found in any field examined
pos	positive
SC	straw-coloured

Histopathology

For explanations see the 'Histopathological Report' in Section 6.

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Test item nomenclature

For reasons of better readability and due to space restrictions, the dose levels used in the study are referred to using the designations given below instead of the full designations as given in Section 2.3.

Group 2: **30 µg BNT162a1/animal**
Group 3: **10 µg BNT162a1/animal**
Group 4: **30 µg BNT162b1/animal**
Group 5: **100 µg BNT162b1/animal**
Group 6: **30 µg BNT162c1/animal**
Group 7: **100 µg BNT162b2/animal**

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1. SUMMARY

1.1 Conduct of study

Test items	1) BNT162a1 2) BNT162b1 3) BNT162b2 4) BNT162c1
Control item	Buffer (PBS/300 mM Sucrose)
Test item batch nos.	1) CoVVAC/090320 2) CoVVAC/100320 3) CoVVAC/160320 4) CoVVAC/130320
Control item batch no.	090320
Test species / Strain / Stock	Rat / Wistar / Crl:WI(Han)
Breeder	(b) (4)
Number and sex of animals	255 animals (126 + 3[1] males and 126 females)
Route of administration	Intramuscular (i.m.) administration into the Musculus biceps femoris using a Microfine+ Syringe 0.5 mL, 0.33 mm (29G) × 12.7 mm (BD, 324824).
Frequency of administration	Groups 1 to 5, and 7: On test days 1, 8 and 15; in total 3 administration days at one-week intervals per animal. Group 6: On test days 1 and 8; in total 2 administration days at a one-week interval per animal. Erroneously treated animals: Single dose on test day 1
Administration volume	Groups 1, 5, and 7: 100 µL/administration site; 2 administration sites In total 200 µL/animal/administration day Groups 2 and 4: 60 µL at one administration site In total 60 µL/animal/administration day

[1] Due to a short-term change of test item and dose level for group 3, three animals had already been treated with the originally planned test item and dose. These three animals were replaced by 3 spare animals for the correct teatment.

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	Group 3: 20 µL at one administration site In total 20 µL/animal/administration day Group 6: 70 µL at one administration site In total 70 µL/animal/administration day Erroneously treated animals: 100 µL/administration site; 2 administration sites In total 200 µL/animal/administration day
Dosages	Groups 1 to 7: Group 1: Control (200 µL Buffer/animal) Group 2: 30 µg BNT162a1/animal Group 3: 10 µg BNT162a1/animal Group 4: 30 µg BNT162b1/animal Group 5: 100 µg BNT162b1/animal Group 6: 30 µg BNT162c1/animal Group 7: 100 µg BNT162b2/animal Erroneously treated animals: 100 µg Test item 2 (BNT162a - 2)/animal
Duration of study	• 5 to 11 adaptation days • 17 test days for groups 1 to 5 and group 7 • 10 test days for group 6 • 3 additional weeks for the animals scheduled for the recovery period

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1.2 Findings

Local tolerance

Treatment period

Local reactions were observed in male and female animals treated intramuscularly with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8. The incidence and severity of the reactions were higher after the 2nd or 3rd injections compared with the 1st injection. The majority of animals revealed very slight to moderate oedema at the injection site(s) following the 1st, 2nd, and/or 3rd injection of the respective test item. A few animals had severe oedema at 48 h after the 2nd injection of **30 µg BNT162c1/animal** or 24 h after the 3rd injection of **100 µg BNT162b2/animal**. The majority of these observations of oedema were resolved or showed signs of resolution by 144 h postdose.

For a few animals, slight or well-defined erythema was also observed in test-item administered animals after the 1st, 2nd, and/or 3rd injection. In addition, after the 2nd or 3rd injection, transient observations of severe erythema were seen in all test article-dosed groups, except for **30 µg BNT162b1/animal**, starting at 96 h after administration. Occasionally these observations of severe erythema continued over several days and/or were associated with wounds or scar tissue in individual animals administered **30 µg BNT162a1/animal** or **30 µg BNT162c1/animal**.

On test day 14, eschar formation was observed at the injection site for 5 male and 6 female animals treated with **30 µg BNT162a1/animal**, which resulted in the decision to move the dosing site to the contralateral limb in 6 animals on test day 15.

The injection site appeared to be painful for 4 of 15 male animals and 12 of 15 female animals treated with **30 µg BNT162a1/animal** on test day 9 and for one male animal also on test day 10.

An indurated and/or thickened injection site, partly accompanied by incrustation, was noted for nearly all animals in all treatment groups at macroscopic inspection at necropsy.

The microscopic examination revealed that test item-related injection site reactions were present in all groups and characterized by mostly moderate inflammation (up to marked) in males

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and moderate inflammation in females. The most severe findings were consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate oedema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac).

Microscopic injection site findings correlated with macroscopic observations of thickening, induration, and incrustation. Injection site findings were consistent with an immune/inflammatory response to intramuscular vaccine administration.

Recovery period

The local skin reactions and the indurations and/or thickenings noted macroscopically for the muscle at the injection site(s) were resolved at the end of the recovery period.

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland, and skeletal muscle) partially or fully recovered at the end of the 3-week recovery period. Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals.

Clinical signs

Treatment and recovery period

None of the male and female animals treated intramuscularly with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal** or **100 µg BNT162b2/animal** on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** on test days 1 and 8 (2 administrations) revealed any test item-related systemic changes in

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behaviour, external appearance, or consistency of faeces.

Mortality

BNT162a1, BNT162b1, BNT162b2, BNT162c1
Treatment and recovery period
No test item-related deaths were noted for any treatment.

Body weight and body weight gain

BNT162a1, BNT162b1, BNT162b2, BNT162c1
Treatment period
Slightly decreased body weights and body weight gain were present in all test-item treated groups compared to controls. Body weight decreases were primarily due to decreases in body weight 24 h after dosing. However, body weight gain during the inter-dosing interval was similar to controls.

In summary, the absolute body weight was affected, but the body weight gain between dosing was not.

Recovery period
No noteworthy changes were noted.

Food and drinking water consumption

Treatment period
BNT162a1 - Group 2
The food consumption of the male and female animals treated with **30 µg BNT162a1/animal** appeared to be slightly decreased by up to 7.2% in test week 1 and 2. The effect is considered to be test item-related.

No test item-related influence was noted on the drinking water consumption by visual appraisal. The consumption was not quantified.

BNT162b1, BNT162b2, BNT162c1
No test item-related influence was observed on the food intake and the drinking water consumption.

Recovery period
No noteworthy changes were noted.

Body temperature

Treatment period
BNT162a1, BNT162b1, BNT162b2, BNT162c1
Intramuscular administration with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8 led to slightly increased body

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temperatures at 4 h p.a. and/or 24 h p.a. compared to the control animals. The effect appeared to be slightly more pronounced in the groups treated with the higher test item dose levels (i.e. groups 2, 5, 6, and 7).

Recovery period
During the recovery period, the body temperature remained at a slightly higher level compared to the control group in all previously test item treated groups.

Haematology and coagulation

Treatment period
The most consistent test item-related haematological changes were dose-related increases in neutrophils and large unstained cells (LUC), which were seen with all test items on test day 17, but were greatest in groups 2, 5 and 7 and were greater in females relative to males. Other test item-related changes included decreases in the absolute and relative reticulocyte count (test day 4 only), platelet count, and red cell mass (HGB, HCT and RBC; test day 17 only), and increases in the numbers of leucocytes, monocytes, eosinophils, basophils and/or fibrinogen concentrations.

BNT162a1 - Groups 2 and 3
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-5.

Recovery period
All changes fully reversed by the end of the recovery phase.

BNT162b1 - Groups 4 and 5
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, eosinophils, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-6.

Recovery period
All changes fully reversed by the end of the recovery phase.

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BNT162c1 - Group 6
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-7.

Recovery period
All changes fully reversed by the end of the recovery phase.

BNT162b2 - Group 7
Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, eosinophils, large unstained cells (LUC), basophils and/or the levels of fibrinogen as given in Text table 4-8.

Recovery period
All changes fully reversed by the end of the recovery phase.

Clinical chemistry

Treatment period
BNT162a1, BNT162b1, BNT162b2, BNT162c1
An elevated plasma activity of gamma-glutamyltransferase (gamma-GT) was noted for all test item-treated groups in comparison to the control group as given in Text table 4-10. There were no macroscopic or microscopic findings consistent with cholestasis or hepatobiliary injury to explain the increased gamma-GT activity.

Further, a decrease in albumin plasma levels and an increase in globulin plasma levels, resulting in an altered albumin/globulin ratio, were observed in all test item treated groups. The changes are consistent with an acute phase response in albumin and globulin where albumin goes down and globulin goes up with inflammation, and the albumin/globulin ratio decreases.

Recovery period
The elevated plasma activity of gamma-GT had subsided in all previously test item-treated groups.

Urinalysis

Treatment and recovery period
No test item-related changes were noted.

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Immunogenicity assessment (performed by BioNTech SE, Germany)	The available data demonstrates that all BNT162 vaccine candidates elicited a SARSCoV-2 spike protein specific antibody response directed against the S1 domain and the RBD sub-domain. Antibody responses detected via ELISA directly translated into neutralizing activity as seen in the VSV/SARS-CoV2-S pseudovirus neutralization test with BNT162 vaccines showing higher antigen-specific antibody titers also displaying more pronounced virus neutralization effect. A comparison of the three RNA platforms with regard to their immunogenicity in rats may not be fully predictive for how they may perform relative to each other in human due to species-specific differences in immunity mechanisms.
Ophthalmological and auditory examination	No changes were noted.
Acute phase proteins	Treatment period **BNT162a1, BNT162b1, BNT162b2, BNT162c1** Elevated serum levels of the acute phase proteins alpha1-acid glycoprotein and alpha2 macroglobulin were noted for all test item-treated groups in comparison to the control group on test day 4 and test day 10 to 17 as given in Text table 4-14 and Text table 4-15. Recovery period The elevated serum levels of alpha1-acid glycoprotein and alpha2 macroglobulin noted during the treatment period had subsided in all previously test item-treated groups.
Cytokines	Treatment and recovery period **BNT162a1, BNT162b1, BNT162b2, BNT162c1** No test item-related changes were noted for any treatment. There were no general differences between the test item-treated groups and the control group and among the various test item-treated groups.
Macroscopic *post mortem* findings	Terminal sacrifice **BNT162a1, BNT162b1, BNT162b2, BNT162c1** Test item-related findings were noted for all test items and all dose levels in male and female animals as given in Text table 4-19, Text table 4-20 and Text table 4-21. All changes noted macroscopically were interpreted to be due to inflammation at the injection site and/or immune activation.

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Recovery sacrifice
All macroscopic findings noted in the spleen had subsided at the end of the 3-week recovery period.

Enlarged iliac lymph nodes were still noted for a few animals at the end of the 3-week recovery period as follows:

Group 4	
(30 μg BNT162b1/animal):	One of 5 females.
Group 5	
(100 μg BNT162b1/animal):	All 5 males, 2 of 5 females.
Group 7	
(100 μg BNT162b2/animal):	One of 5 males, 3 of 5 females.

Organ weights

Terminal sacrifice
BNT162a1, BNT162b1, BNT162b2, BNT162c1
The macroscopic findings of enlarged spleens correlated with increased relative and absolute spleen weights and are identified in Text table 4-22.

Recovery sacrifice
There were no noteworthy differences in the organ weights between the previously test item-treated animals and the control animals after 3-weeks of recovery.

Histopathology

Terminal sacrifice
Test item-related microscopic findings at the end of dosing were evident in injection sites and surrounding tissues, increased cellularity of germinal centres and increased plasma cells in the draining (iliac) lymph nodes, bone marrow, spleen, and liver.

For details on the findings at the injection sites refer to 'Local tolerance' further above.

Test item-related findings in the draining (iliac) lymph node were characterized by increased cellularity of the follicular germinal centres and increased plasma cells (plasmacytosis) which were variably present in all groups.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary haematopoiesis in the spleen (which correlated with increased spleen size and weight), and a test item-related vacuolation of hepatocytes in the portal regions of the liver were present in all groups. The liver findings were not associated with changes in markers of hepatocyte injury

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(e.g. ALAT). While gamma-GT was elevated in test-item treated animals, it is not a marker of hepatocyte injury.

The test item-related findings are summarised in Text table 4-24, Text table 4-25 and Text table 4-26.

Recovery sacrifice

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland; skeletal muscle) and spleen were partially or completely recovered in all animals at the end of the recovery period. Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals, being less severe (minimal to mild) if not resolved; plasmacytosis in the iliac lymph node was less severe and present in fewer groups (**30** or **100 µg BNT162b1/animal** or **100 µg BNT162b2/animal**), indicating partial or complete recovery.

The test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary haematopoiesis in the spleen, and the vacuolation of hepatocytes in the portal regions of the liver were fully recovered.

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1.3 Conclusion

Intramuscular administration of 4 LNP-formulated RNA vaccines (based on 3 LNP-formulated RNA platforms) encoding viral proteins once weekly for 2 or 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity and produced the expected local inflammatory reaction. Treatment groups included: **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** on test days 1 and 8 (2 administrations).

No test item-related deaths were noted for any treatment. There were no test-item related ophthalmologic or auditory alterations. None of the animals of any treatment group revealed any test item-related systemic changes in behaviour, external appearance, or consistency of faeces.

Clinical findings included slightly decreased body weights and body weight gain and transient slight elevations in body temperatures at 4 and 24 h after dosing for all test-item treated groups compared to controls. Body weight decreases were primarily due to decreases in body weight 24 h after dosing; however, body weight gain during the inter-dosing interval was similar to controls. A slightly reduced food consumption was noted for the animals treated with **30 µg BNT162a1/animal** in test weeks 1 and 2.

Test-article related injection site observations included oedema, erythema, and induration; oedema was the most common finding, followed by erythema, and very rarely induration. The incidence was higher and observations were more severe after the second and or third dose administration compared to the first administration, but resolved prior to subsequent dosing and were fully recovered at the end of the 3-week recovery period. Macroscopic findings at the injection sites included induration or thickening, occasionally accompanied by incrustation, which was noted for nearly all test article-treated animals. This correlated microscopically to inflammation in all test article-administered animals. Inflammation was mixed to mononuclear with variable fibrosis, oedema, and myofiber degeneration (rare necrosis).

Inflammation was most severe in animals dosed with **100 µg BNT162b1/animal** or **100 µg BNT162b2/animal**, followed by **30 µg BNT162a1/animal**. The findings were typical of an inflammatory response to vaccine antigen and lipid nanoparticle. Inflammation was occasionally evident extending into tissues adjacent to the injection site. Inflammation at the injection site was accompanied by elevations in circulating white blood cells (granulocytes, monocytes, and LUC) and acute phase proteins (fibrinogen, alpha-2 macroglobulin, and alpha-1 acid glycoprotein).

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At the end of the 3-week recovery phase, all clinical injection site findings, clinical pathology findings and macroscopic observations had resolved and there was evidence of recovery of the injection site inflammation microscopically. The injection site findings were not interpreted as adverse because of limited severity, lack of systemic findings, and absence of clinical signs of lameness.

Test-article related macroscopic enlargement of the draining (iliac) lymph nodes was evident at the end of dosing. Microscopically, this finding correlated with increased cellularity of germinal centres and increased plasma cells in the draining (iliac) lymph node and is an anticipated immune response to the administered vaccine and LNP. At the end of the 3-week recovery, a few animals treated with **BNT162b1** or **BNT162b2** (30 μg and/or 100 μg/animal) still had slightly enlarged iliac lymph nodes. All other test item-related changes had subsided.

Effects considered secondary to immune activation/acute phase responses and inflammation at the injection site included transient reticulocyte decreases (test day 4 only), minimal decreases in RBC, HGB, and HCT on test day 17 only, and sporadic small magnitude decreases in platelets. Platelet reductions were likely due to inflammation-related platelet activation and consumption and were un-associated with other alterations in haemostasis. These effects had subsided after the 3-week recovery period.

Test-article related macroscopic enlargement of spleen and associated absolute and relative spleen weights correlated microscopically to increased haematopoiesis; this finding was resolved at the end of the 3-week recovery period. Increased haematopoiesis was also evident in the bone marrow. Both findings were secondary to inflammation at the injection site and were fully resolved at the end of the 3-week recovery period.

Test-article related microscopic vacuolation of portal hepatocytes was present in all groups, with a higher incidence in females than males for all but the groups that were administered **100 µg/animal BNT162b1** or **BNT162b2**. This finding was not adverse because it was unassociated with alterations in hepatic function (e.g. no elevations in ALAT) and was fully reversed at the end of the 3-week recovery period. This change may be related to hepatic clearance of the pegylated lipid in the LNP.

No test item-related changes were observed for cytokine serum levels.

Elevations in GGT were evident in all test-item treated animals. There were no macroscopic or microscopic findings consistent with cholestasis or hepatobiliary injury to explain the increased gamma-GT activity which was completely resolved at the end of the 3-week recovery period.

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Immunogenicity assessment demonstrated that all BNT162 vaccine candidates elicited a SARSCoV-2 spike protein specific antibody response directed against the S1 domain and the RBD sub-domain. Antibody responses detected via ELISA directly translated into neutralizing activity as seen in the VSV/SARS-CoV2-S pseudovirus neutralization test with BNT162 vaccines showing higher antigen-specific antibody titers also displaying more pronounced virus neutralization effect.

In conclusion, administration of vaccine candidates **BNT162a1**, **BNT162b1**, **BNT162b2**, or **BNT162c1** via intramuscular injections weekly for 2 or 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity and produced nonadverse inflammatory changes at the injection sites and the draining lymph nodes, increased haematopoiesis in the bone marrow and spleen, and clinical pathology changes consistent with an immune response or inflammation in the injection sites. The findings in this study are reversible, consistent with those typically associated with the intramuscular administration of antigens and/or LNPs.

(b) (6), (b) (4)

17 Sep 2020
Date

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2. GENERAL INFORMATION

2.1 Aim of study

The aim of the study was to obtain information on the toxicity of four vaccines based on three LNP-formulated RNA vaccine platforms encoding for viral proteins administered once weekly by intramuscular administration to rats and to assess the reversibility of any effect after a 3-week recovery period.

2.2 Duration of study

- 5 to 11 adaptation days
- 17 test days for groups 1 to 5 and group 7
- 10 test days for group 6
- 3 additional weeks for the animals scheduled for the recovery period

2.3 Test items and control

2.3.1 Control (for group 1)

Designation	Buffer (PBS/300 mM Sucrose)
Batch no.	090320
Receipt no.	69570 (one vial with a gross weight of 66.76 g)
Date of receipt	13 March 2020
Characteristics	Liquid
Storage conditions	At +2°C to +8°C
Stability/Retest date	No data available to (b) (4). No Certificate of Analysis was available to (b) (4).
Retention sample	Stored in (b) (4) archives.

2.3.2 Test item 1 (for groups 2 and 3)

Designation	"RBL063.3" (BNT162a1)
Content	LNP formulated uRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162a – 1")
Batch no.	CoVVAC/090320
Receipt no.	69571 (100 vials with 500 µL each)

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Date of receipt	13 March 2020
Characteristics	Frozen liquid (at receipt at (b) (4))
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	517 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in (b) (4) archives.

2.3.3 Test item 3 (for groups 4 and 5)

Designation	"RBL020.3" (BNT162b1)
Designation	LNP formulated modRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162b - 1")
Batch no.	CoVVAC/100320
Receipt no.	69573 (100 vials with 500 µL each)
Date of receipt	13 March 2020
Characteristics	Frozen liquid (at receipt at (b) (4))
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	508 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in (b) (4) archives.

2.3.4 Test item 4 (for group 7)

Designation	"RBP020.1" (BNT162b2)
Designation	LNP formulated modRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162b - 2")
Batch no.	CoVVAC/160320

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Receipt no.	69580 (100 vials with 500 µL)
Date of receipt	20 March 2020
Characteristics	Frozen liquid (at receipt at (b) (4))
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	554 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in (b) (4) archives.

2.3.5 Test item 5 (for group 6)

Designation	"RBS004.3" (BNT162c1)
Designation	LNP formulated saRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162c - 1")
Batch no.	CoVVAC/130320
Receipt no.	69581 (70 vials with 500 µL)
Date of receipt	20 March 2020
Characteristics	Frozen liquid (at receipt at (b) (4))
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	430 µg RNA/mL For further details see the Certificate of Analysis in Appendix 1.
Retention sample	Stored in (b) (4) archives.

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2.3.6 Test item 2

Test item 2 was not scheduled to be used as test item in the study. However, 3 animals were treated erroneously with this test item (see also Section 3.7).

Designation	"RBL063.1" (BNT162a - 2)
Designation	LNP formulated modRNA encoding the RBD subunit of SARS-CoV-2 S protein ("BNT162a - 2")
Batch no.	CoVVAC/110320
Receipt no.	69572 (100 vials with 500 µL)
Date of receipt	13 March 2020
Characteristics	Frozen liquid (at receipt at (b) (4))
Storage conditions	At -70°C or colder
Stability/Retest date	September 2020
Concentration	481 μg RNA/mL
Retention sample	Stored in (b) (4) archives.

2.4 Identification of the test items

After receipt at (b) (4), the test items were inspected. Batch numbers, amounts, and characteristics (colour and consistency) were determined and compared with information given by the Sponsor (see text table below). Identification sheets were filed with the raw data.

Text table 2-1: Identification of the test item

Test item / Control	Parameter	(b) (4) identification#	Sponsor identification##
Control: Buffer (PBS/300 mM Sucrose)	colour consistency	clear liquid	white to off-white suspension
BNT162a1	colour consistency	slightly turbid liquid	white to off-white suspension
BNT162b1	colour consistency	slightly turbid liquid	white to off-white suspension
BNT162b2	colour consistency	slightly turbid liquid	white to off-white suspension
BNT162c1	colour consistency	slightly turbid liquid	white to off-white suspension

Identified before usage, in thawed condition, at room temperature.
According to Certificates of Analysis, for the thawed conditions of the test items.

No further identification was performed by (b) (4).

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2.5 Sponsor / Test Facility / Responsible personnel

Sponsor	BioNTech RNA Pharmaceuticals An der Goldgrube 12 55131 Mainz Germany
Sponsor's contact person	(b) (6)
Test Facility	(b) (4)
Branch facility	(b) (4)
Study Director	Until 31 May 2020 (b) (6), (b) (4) As of 01 June 2020 (b) (6), (b) (4)
Deputy Study Director	(b) (6), (b) (4)
Test Facility Management	
Haematology / Clinical chemistry / Coagulation / Cytokine Analysis / Blood sampling	
Acute phase protein analysis	
Veterinarian / Macropathology	
Histopathology	
Statistics	
Quality Assurance Unit (QAU)	

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2.6 Rules and regulations

2.6.1 Good Laboratory Practice

The study was performed in compliance with the 'Good Laboratory Practice' regulations (see the Statement of Compliance on page 5 and the enclosed 'GLP Certificate of the Test Facility (b) (4)' in Appendix 3).

2.6.2 Standard Operating Procedures and staff safety

Standard Operating Procedures (SOPs)	All work was carried out according to Standard Operating Procedures which were followed for all stages of the study. The SOPs could be inspected in those divisions, which were engaged in the study and in the Quality Assurance Unit (QAU).
Staff safety	The standard safety precautions operating within the department were applied to this study.

2.6.3 Archiving and storage

Archives of data and specimens

During the study

All data generated at the Branch Facility:

In the depot
(b) (4)

All remaining data:

In the depot
(b) (4)

After reporting

The final report and the amendment no. 1 to final report will be archived by the Sponsor.

A copy of the final report, the amendment no. 1 to final report and all specimens, written raw data, and other study-related documents listed in the Study Plan section 'Study Materials to be Archived' are stored in the (b) (4) archives. The duration of storage (15 years) will be in compliance with the GLP regulations as stated in the German Chemicals Act ("Chemikalien-gesetz").

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All archived study materials will be destroyed after the 15-year GLP storage period unless the Sponsor requests otherwise.

Upon expiry of the 15-year archiving period, the Sponsor will be given three weeks' notice before the study documentation and samples are destroyed by (b) (4). The Sponsor must respond within the 3-week notification period if testing documentation is to be transferred to the Sponsor (shipping fees will be billed). If (b) (4) does not receive any response from the Sponsor, the study documentation and samples will be destroyed.

To avoid any doubt, it is the responsibility of the Sponsor to provide (b) (4) with a valid contact. The archived documentation and samples will be destroyed without Sponsor notification after 15.5 years of archiving if (b) (4) cannot contact the Sponsor because

- a valid Sponsor contact has not been provided
  or
- the Sponsor company no longer exists
  or
- (b) (4) has not been advised of the legal successor.

Three months after the issuance of the Final Study Report, any samples or aliquots not listed in the Study Plan section 'Study Materials to be Archived' and still remaining at (b) (4) will be listed. This list will be forwarded to the Sponsor who will decide which of these samples or aliquots will be dispatched and which samples or aliquots will be destroyed at (b) (4).

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2.7 Study dates

Code number of the study in the raw data: 38166

Start of study

Date of Study Plan: 16 March 2020

Study Plan amendments: No. 1, dated 17 March 2020
No. 2, dated 23 March 2020
No. 3, dated 25 March 2020
No. 4, dated 03 April 2020
No. 5, dated 06 April 2020
No. 6, dated 08 April 2020
No. 7, dated 20 April 2020
No. 8, dated 29 May 2020
No. 9, dated 18 June 2020

Text table 2-2: In-life Schedule - Study dates

Animals	First administration	End of in-life period
All main study animals of groups 1, 2 and 4	17 March 2020	02 April 2020
All recovery animals of groups 1, 2 and 4	17 March 2020	23 April 2020
All main study animals of groups 3, 5 and 7	23 March 2020	08 April 2020
All recovery animals of groups 3, 5 and 7	23 March 2020	29 April 2020
All main study animals of group 6	23 March 2020	01 April 2020
All recovery animals of group 6	23 March 2020	22 April 2020
Three erroneously treated animals (non-GLP)	23 March 2020	26 March 2020
All satellite animals of groups 1, 2 and 4	24 March 2020	09 April 2020
All satellite animals of groups 3, 5 and 7	14 April 2020	30 April 2020
All satellite animals of group 6	14 April 2020	23 April 2020

Date of Final Report: 01 July 2020

Date of Amendment No. 1 to Final Report: 17 September 2020

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2.8 Study Plan deviations

The study was conducted in accordance with the Study Plan and 9 Study Plan amendments. There was no major deviation from the Study Plan and the Study Plan amendments. However, the following minor deviations were noted:

Animals

A few male and female animals exceeded the allowed body weight range of 10% of the mean weight for each sex at the time of selection. This deviation was due to the limited availability of animals that fully met the required body weight criteria from the breeder.

Two (2) of the 10 delivered female satellite animals designated for blood sampling via the femoral vein catheter showed inflammations at the vascular access button. Hence, these animals were excluded from the study. However, 9 of the 10 animals originally delivered were needed to start dosing as scheduled. Therefore, a female spare animal from the main study animals that was not equipped with a femoral vein catheter was inserted into the satellite group (no. 215). Blood sampling was performed by means of retrobulbar vein puncture from this animal.

Animal housing

A malfunctioning of the air conditioning system caused relative humidity values in the animal room that temporarily fell slightly below the lower admissible limit of 40% on a few test days. The room temperature did not exceed the maximum range during the study period.

Administration

On test day 15, the male animals nos. 32, 34, 37, 39 and 42, and the female animal no. 60 (all of group 2) were dosed intramuscularly in the left hind leg contrary to the previous administrations, which were performed in the right hind limb. This change was due to local tolerance findings (eschar formation) which developed after administration on test day 8. In the affected animals, both administration sites were fixed at necropsy and processed for histological examinations.

Organ weights

The spleen of the female animal no. 144 was not weighed during necropsy.

These minor deviations that were not covered by Study Plan amendments did not affect the validity and integrity of the scientific results obtained during the study.

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3. MATERIALS AND METHODS

3.1 Animals

Wistar Han rats supplied by (b) (4) were used in this study. The satellite animals were supplied with a pre-implanted femoral vein catheter for repeated blood sampling.

An initial health check was performed upon delivery of the animals. Only animals free of signs of illness were selected for the study.

The animals were allocated to the test groups based on body weight by means of a computerized randomization program (see Section 3.7). Animals with a body weight at the extremes of the weight distribution, if any, were excluded and replaced by healthy spare animals. No replacements occurred after the first dose had been administered.

Test species / Strain / Stock	Rat / Wistar / Crl:WI(Han) All satellite animals (except for no. 215, see Section 2.8) were equipped with a vascular access button to the femoral vein by the breeder.
Breeder	(b) (4)
Number and sex of animals	255 animals (129 males and 126 females) <u>Main study (MS)</u> 143 animals (70 + 3 males and 70 females) Due to the short-term change of test item and dose level - from 100 µg Test item 2 (BNT162a2)/animal to 10 µg BNT162a1/animal - for group 3 (according to Study Plan amendment no. 2), three male animals had already been dosed with the originally planned dose of 100 µg Test item 2 (BNT162a2)/animal. These three animals of group 3 were replaced by 3 spare animals (see also Section 3.7). <u>Recovery period (RP)</u> 70 animals (35 males and 35 females) In addition, 20 spare animals (10 males and 10 females) were available for possible replacement. Three of the male spare animals were used to replace the erroneously dosed animals (see above, and Text table 3-2). One of the female spare animals was used as a satellite animal (no. 215, see Section 2.8).

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	Satellite animals (SA) 42 animals (21 males and 21 females) In addition, 6 spare satellite animals (3 males and 3 females) were available for possible replacement. The satellite animals were supplied in two separate shipments (10 animals per sex for groups 1/2/4, and 14 animals per sex for groups 3/5/6/7) to (b) (4). Two (2) of the 10 animals of the shipment for groups 1/2/4 showed inflammations at the vascular access button and were excluded from the study. As 9 animals were needed to start dosing as scheduled, one female spare animal from the main study animals not equipped with a vascular access button was used as satellite animal (see further above).
Age (at 1st dosing)	Groups 1, 2, and 4: Males and females: 54 days Groups 3, 5, 6, and 7: Males and females: 60 days
Body weight (at 1st dosing)	Males: 252.8 to 343.9 g Females: 188.3 to 267.3 g
Selection of species	The rat is a commonly used rodent species for toxicity studies. It can receive the full human dose and develops an immune response similar to the expected human response after vaccination.
Identification of animals	After randomisation, each rat received a continuous number on the tail, either by tattoo or marker. Additionally, the animal cages were labelled with study number, animal ID number, sex, type of study, route of administration, and treatment group.
Adaptation period	Groups 1, 2, and 4: 5 days Groups 3, 5, 6, and 7: 11 days

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3.2 Housing and feeding

3.2.1 Diet

A certified commercial pellet diet (ssniff® R/M-H V1534, ssniff Spezialdiäten GmbH, 59494 Soest, Germany; see Appendix 2: 'Composition of the Diet') served as food. The food was offered *ad libitum*. Food residue was removed and weighed.

Periodic analysis of the food for contaminants based on EPA/USA[2] is conducted at least twice a year by (b) (4) [3] (see Appendix 2: 'Limitation for Contaminants in the Diet'). Certificates of analysis of the composition and for contaminants were provided by the manufacturer and were included in the raw data.

3.2.2 Drinking water

Drinking water was offered *ad libitum*.

Samples of drinking water are taken by Wasserwerk Wankendorf and periodic analyses are performed by (b) (4) according to the 'Deutsche Trinkwasser-verordnung 2001' [German Regulations on Drinking Water 2001][4] (see Appendix 2: 'Limitation for Contaminants in the Drinking Water').

In addition, drinking water samples taken at (b) (4) are analysed by (b) (4) once a year for means of bacteriological investigations according to the 'Deutsche Trinkwasserverordnung 2001, Anlage 1' [German Regulations on Drinking Water 2001, Addendum 1].

3.2.3 Housing

The animals were kept singly in MAKROLON cages (type III plus) with a basal surface of approximately 39 cm × 23 cm and a height of approximately 18 cm at a room temperature of 22°C ± 3°C (maximum range) and a relative humidity of 55% ± 10% (maximum range). Deviations from the maximum range caused for example during cleaning procedures were dealt with in SOPs.

The rooms were lit (about 150 lux at approx. 1.5 meters room height) and darkened for periods of 12 hours each.

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2 EPA/USA, Proposed Health Effects Test Standards for Toxic Substances Control Act Test Rules, Federal Register 44, 27334 - 27375, May 1979.

3 (b) (4)

4 Version from 02 August 2013, revised on 20 December 2019.

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Granulated textured wood (Granulat A2, J. Brandenburg, 49424 Goldenstedt, Germany) was used as bedding material for the cages. The cages were changed and cleaned once a week.

Periodic analysis of the bedding material for contaminants based on EPA/USA is conducted at least once a year by (b) (4) (see Appendix 2: 'Limitation for Contaminants in the Bedding Material').

3.3 Dose selection

The dose levels for this study had been selected in agreement with the Sponsor based on the anticipated clinical doses.

3.4 Test item preparation

The test items were delivered ready-to-use.

The LNP suspensions for dosing were used within 6 hours after thawing.

Protocol:

1. The test item vials required were thawed by removing from the -80°C ±8°C storage and allowed to warm to room temperature (approximately 30 minutes).
2. Each vial was mixed by gently inverting three times. The vials were neither mixed vigorously nor vortexed.
3. The vial's flip cap was flipped off.
4. The needle was inserted through the stopper into a vial and the appropriate volume per animal withdrawn. The procedure was repeated until the total needed volume per animal had been obtained. A new syringe (including needle) was used for each animal.
5. After the last administration of a day, any remaining volumes of the thawed test items were discarded; remnants were not re-frozen or re-used.

3.5 Test item formulation analysis

As the test items were delivered ready-to-use no formulation analysis was required.

3.6 Administration

Route of administration	Intramuscular (i.m.) administration into the *Musculus biceps femoris* using a Microfine+ Syringe 0.5 mL, 0.33 mm (29G) × 12.7 mm (BD, 324824).

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Frequency of administration

Groups 1, 2, 3, 4, 5 and 7:
On test days 1, 8 and 15; in total 3 administration days at one-week intervals per animal.

Group 6:
On test days 1 and 8; in total 2 administration days at a one-week interval per animal.

Erroneously treated animals:
Single dose (2 administration sites) on test day 1

Administration volume

Groups 1 to 7:

Text table 3-1: Administration volume

Group	Number of administration sites	Administration volume per administration day [µL]	
		Per site	Per animal
1	2	100	200
2	1	60	60
3	1	20	20
4	1	60	60
5	2	100	200
6	1	70	70
7	2	100	200

Erroneously treated animals:
100 µL/administration site; 2 administration sites
In total 200 µL/animal/administration day

Dosages

Groups 1 to 7:
Group 1: Control (200 µL Buffer/animal)
Group 2: 30 µg BNT162a1/animal
Group 3: 10 µg BNT162a1/animal
Group 4: 30 µg BNT162b1/animal
Group 5: 100 µg BNT162b1/animal
Group 6: 30 µg BNT162c1/animal
Group 7: 100 µg BNT162b2/animal

Erroneously treated animals:
100 µg Test item 2 (BNT162a2)/animal

See the text table in Section 3.7 for details.

Selection of route of administration

According to clinical use. The intramuscular route is the anticipated route for human exposure to the test item.

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3.7 Group size and dose levels

The animals were allocated to 7 test groups by means of a computer generated randomisation program[5] and treated as given in the text table below.

Text table 3-2: Group distribution and dosing scheme

Group	Dose level [µg/animal] (Test item / Control)	Number and sex of animals MS + RP + SA	Animal no.		
			MS	RP	SA
1	0 (Buffer) Control	10 + 5 + 3 m 10 + 5 + 3 f	1 - 10 16 - 25	11 - 15 26 - 30	211 - 213 214 - 216
2	30 (BNT162a1)	10 + 5 + 3 m 10 + 5 + 3 f	31 - 40 46 - 55	41 - 45 56 - 60	217 - 219 220 - 222
3	10 (BNT162a1)	10 + 5 + 3 m 10 + 5 + 3 f	61 - 70 76 - 85	71 - 75 86 - 90	223 - 225 226 - 228
4	30 (BNT162b1)	10 + 5 + 3 m 10 + 5 + 3 f	91 - 100 106 - 115	101 - 105 116 - 120	229 - 231 232 - 234
5	100 (BNT162b1)	10 + 5 + 3 m 10 + 5 + 3 f	121 - 130 136 - 145	131 - 135 146 - 150	235 - 237 238 – 240
6	30 (BNT162c1)	10 + 5 + 3 m 10 + 5 + 3 f	151 - 160 166 - 175	161 - 165 176 - 180	241 - 243 244 - 246
7	100 (BNT162b2)	10 + 5 + 3 m 10 + 5 + 3 f	181 - 190 196 - 205	191 - 195 206 - 210	247 - 249 250 - 252
Erroneously treated animals[#1]	100 (Test item 2: BNT162a2)	0 + 0 + 3 m	—	—	253 - 255

m male
f female
MS Main study
RP Recovery period
SA Satellite animals for cytokine analysis (except animals nos. 253 to 255)

[#] The treatment of group 3 was changed from 100 µg Test item 2/animal, as stipulated in the original Study Plan (Test item 2 was designated "RBL063.1" (BNT162a - 2), see Section 2.3.6), to 10 µg BNT162a1/animal as per Amendment no. 2 to the Study Plan, dated 23 March 2020, the date of start of treatment for group 3 (see Section 2.7). As the treatment change for group 3 was communicated at very short notice, 3 male animals had already been dosed with 100 µg Test item 2 (BNT162a2)/animal as originally planned on test day 1. These three animals were replaced by 3 spare animals in group 3. The erroneously treated animals received the new animal numbers given above. Test item 2 (BNT162a2) was not further used in the study.

The satellite animals of groups 1 to 7 were used for blood sampling only (see Section 3.8.7.5). Following the last blood sampling, these animals were sacrificed but not dissected.

[5] Provantis® Integrated preclinical software, version 10.2, Instem LSS Ltd, Stone, Staffordshire ST15 0SD, United Kingdom.

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The erroneously administered animals (nos. 253 to 255) were observed for 48 h post dosing under Non-GLP conditions. Body weight (test day 1, and 24 and 48 h post injection), body temperature (24 and 48 h post injection) and local tolerance (24 and 48 h post injection) were recorded. Based on these observations, the Sponsor decided how to further proceed: These animals were neither subjected to laboratory examinations nor to blood sampling for cytokine analysis. The observations were only performed for scientific interest and were not part of the GLP study. The gathered observations are not included in this report, but were communicated separately to the Sponsor.

3.8 Observations

All in-life examinations described in the following subsections pertain only to the main study and recovery animals, i.e. the satellite animals were excluded from these examinations.

Dated and signed records of all activities related to the day-to-day running and maintenance of the study within the animal unit as well as to the group observations and examinations outlined in the Study Plan were recorded in appropriate documentation. In addition, observations related to individual animals were made throughout the study and recorded.

The following sections describe the observations made during the course of the study.

3.8.1 Clinical signs

The animals were observed individually before and after dosing at each time of dosing for any signs of behavioural changes, reaction to treatment or illness.

In addition, the animals were checked regularly throughout the working day from 7:00 a.m. to 3:45 p.m. (i.e. starting approximately at 7:00 a.m., 9:00 a.m., 11:00 a.m., 1:00 p.m. and 3:00 p.m.). On Saturdays and Sundays, the animals were checked regularly from 7:00 a.m. to 11:00 a.m. with a final check performed at approximately 3:30 p.m. (i.e. starting at approximately 7:00 a.m., 9:00 a.m., 11:00 a.m., and 3:00 p.m.).

Cageside observations included skin/fur, eyes, mucous membranes, respiratory and circulatory systems, somatomotor activity and behaviour patterns. The onset, intensity and duration of any signs observed were recorded.

Dated and signed records of appearance, change and disappearance of clinical signs of individual animals were maintained on clinical history sheets.

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Special attention was paid to the local tolerance at the injection sites (see Section 3.8.3 for details on the observation of erythema/eschar, oedema, induration/hardening).

3.8.2 Mortality

Further checks were made early in the morning and again in the afternoon of each working day to look for dead or moribund animals. On Saturdays and Sundays, a similar procedure was followed with a final check at approximately 3:30 p.m.

These provisions allowed for recording of premortal symptoms in detail and for performing post mortem examinations as soon as possible after exitus. However, no premature deaths occurred and no premature sacrifice was necessary.

3.8.3 Local tolerance

The local tolerance of the test item at the injection site was recorded for all main study and recovery animals at the following times:

- 4 h after each injection
- 24 h after each injection
- 48 h after each injection

  As irritations were still present at 48 h after injection, the observations of the respective animal was extended to every 48 h until the irritation had resolved (i.e. 96 h p.a. and 144 h p.a. if necessary).

The injection sites were assessed for

- erythema and eschar formation
- oedema formation
- induration/hardening following palpation

The reactions were scored with a grading similar to that based on DRAIZE (Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics, Association of Food and Drug Officials of the United States, Austin, Texas, 1959) as given in detail in the text tables following on the following page.

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Text table 3-3: Grading of erythema and eschar formation

Erythema and eschar formation	Value
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beef redness) or eschar formation (injuries in depth) preventing erythema reading	4

Text table 3-4: Grading of oedema formation

Oedema formation	Value
No oedema	0
Very slight oedema (barely perceptible)	1
Slight oedema (edges of area well defined by definite raising)	2
Moderate oedema (raised approx. 1 millimetre)	3
Severe oedema (raised more than 1 millimetre and extending beyond area of exposure)	4

Text table 3-5: Grading of induration/hardening

Grade of induration/hardening	Value
No induration/hardening	0
Very slight induration/hardening (barely perceptible)	1
Slight induration/hardening	2
Moderate induration/hardening	3
Severe induration/hardening	4

If there were two injection sites per animal (left/right side), individual values for each of the two injection sites were only recorded in case the gradings of the sites were different (e.g. '0/1'). If the gradings of the two injection sites were identical only one scoring was recorded.

In addition, any signs of pain were recorded as general observations of local tolerance.

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3.8.4 Body weight

The body weight of each rat was recorded at the following times:

- at group allocation
- prior to each administration: on test days 1, 8, and 15 (if applicable)
- one day after each administration: on test days 2, 9, and 16 (if applicable)
- twice weekly during the recovery period
- at autopsy (i.e. during the process of necropsy, i.e. after fasting overnight and exsanguination, see Section 3.8.10.1 for details)

3.8.5 Food and drinking consumption

The quantity of food left by individual animals was removed, weighed, and recorded on a weekly basis throughout the experimental period. The residue was discarded.

The food intake per animal (g/animal/week) was calculated using the total amount of food given to and left by each rat in each group on completion of a treatment week. Weekly mean values were calculated for individual animals.

The relative food consumption (in g/kg b.w./day) was calculated as follows:

$$\text{Relative food consumption (g/kg b.w./day)} = \frac{\text{Total food given (g) - Total food left (g)}}{\text{Number of animal days}^{\#} \times \text{Body weight (kg)}}$$

[#] The term 'animal days' counts one animal day for each animal alive for a whole day; it is assumed that on the day of death an animal does not eat.

The drinking water consumption was monitored daily by visual appraisal throughout the study. The consumption was not quantified.

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3.8.6 Body temperature

The body temperature was determined using an anal probe at the times stated in the text table below.

Text table 3-6: Time points for body temperature measurement

Test day	Time points for body temperature measurement relative to dosing	Groups or animal number	Main study animals	Recovery animals
1	4 hours after 1st injection	1 to 7	X	X
2	24 hours after 1st injection	1 to 7	X	X
3	48 hours after 3rd injection[#]	No. 171		
8	4 hours after 2nd injection	1 to 7	X	X
9	24 hours after 2nd injection	1 to 7	X	X
15	1 week after last administration	6 and 7		X
15	4 hours after 3rd injection	1 to 5	X	X
16	24 hours after 3rd injection	1 to 5	X	X
17	48 hours after 3rd injection[##]	No. 149		
22	1 week after last administration	1 to 5		X
22	2 weeks after last administration	6 and 7		X
29	2 weeks after last administration	1 to 5		X
29	3 weeks after last administration	6 and 7		X
36	3 weeks after last administration	1 to 5		X

[#] The female animal no. 171 (group 6) revealed a body temperature of 40.0°C on test day 2 (i.e. 24 h after 1st injection on test day 1). For this animal, an additional body temperature measurement was conducted on test day 3 at 48 h after injection.

[##] The female animal no. 149 (group 5) revealed a body temperature of 40.2°C on test day 16 (i.e. 24 h after 3rd injection on test day 15). For this animal, an additional body temperature measurement was conducted on test day 17 at 48 h after injection.

3.8.7 Laboratory examinations

Blood samples were taken from the retrobulbar venous plexus under isoflurane anaesthesia from animals fasted overnight. The blood samples were collected into tubes as follows:

EDTA anticoagulant (whole blood).....for haematological investigations
Citrate anticoagulant (plasma)..... for coagulation tests
Li-Heparin anticoagulant (plasma) .....for clinical chemistry tests
Serum (no anticoagulant) .....for acute phase proteins and dose exposure

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The male animal no. 130 died during the blood withdrawal on test day 17. The blood sample intended for clinical chemistry tests was obtained by heart puncture from this animal. As a result, the plasma levels of phosphate and potassium, and the enzyme activities of ASA and LDH were far beyond the normal range for these parameters. Therefore, these data were excluded from statistical analysis (marked by 'E!' in Table 1-2).

3.8.7.1 Haematology

The blood samples were obtained as follows:

- On test day 4:	The first 5 surviving main study animals per sex and group and all recovery animals (n = 10 per group).
- At main study termination (on the day of dissection):	All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection):	All recovery animals (n = 5 per group).

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The haematological parameters listed in the text table below were determined.

Text table 3-7: Haematological parameters

Parameter	Unit	Instrument
Haemoglobin content (HGB)	mmol/L	ADVIA™ 120 Siemens Diagnostics GmbH 35463 Fernwald Germany
Erythrocytes (RBC)	$10^6/\mu L$	
Leucocytes (WBC)	$10^3/\mu L$	
Reticulocytes (Reti), relative	%	
Reticulocytes (Reti), absolute	$10^3/\mu L$	
Platelets (PLT)	$10^3/\mu L$	
Haematocrit value (HCT)	%	
Differential blood count (relative)[#]	%	
Differential blood count (absolute)[#]	$10^3/\mu L$	
Mean corpuscular volume (MCV)	fL	
Mean corpuscular haemoglobin (MCH)	fmol	
Mean corpuscular haemoglobin concentration (MCHC)	mmol/L	
Mean platelet (thrombocyte) volume (MPV)	fL	
Relative volume of thrombocytes / Plateletcrit (PCT)	%	
Platelet distribution width (PDW)	%	
Red cell distribution width (RDW)	%	
Mean platelet component (MPC)	g/dL	

[#] Neutrophilic, eosinophilic and basophilic granulocytes, lymphocytes, and monocytes. Large unstained cells were simultaneously quantified during measurement of the differential blood count.

Following the haematological examinations using the ADVIA system, blood smears were prepared from all samples, dried, and stained as given in the text table on the following page.

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Text table 3-8: Staining of blood smears

Dissection	Group	Number of stainings	
		Pappenheim	Brilliant Cresyl blue
Test day 4	Groups 1, 2 and 4	1	0
	Groups 3, 5, 6 and 7	1	0
Main study	Groups 1, 2 and 4	1	1
	Group 6	1	1
	Groups 3, 5 and 7	1	1
Recovery	Groups 1, 2 and 4	1	1
	Group 6	1	1
	Groups 3, 5 and 7	1	1

The stained blood smears may be evaluated, if requested by the Sponsor (details are to be stated in a Study Plan amendment). So far, no evaluation of blood smears was performed by (b) (4).

3.8.7.2 Coagulation

The blood samples were obtained as follows:

- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group)

The coagulation parameters listed in the text table below were determined.

Text table 3-9: Coagulation parameters

Parameter	Unit	Instrument
Prothrombin time (PT)	sec	Amax Destiny Plus™ Tcoag Deutschland GmbH 32657 Lemgo, Germany
Activated partial thromboplastin time (aPTT)	sec	
Fibrinogen	mg/dL	

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3.8.7.3 Clinical chemistry

The blood samples were obtained as follows:

- On test day 4: The first 5 surviving main study animals per sex and group and all recovery animals (n = 10 per group).
- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group).

The clinical chemistry parameters listed in the text table below were determined.

Text table 3-10: Clinical chemistry parameters

Parameter	Unit	Instrument / Method
Albumin	g/L plasma	KONELAB 30i (see below)
Globulin	g/L plasma	By subtraction
Albumin/globulin ratio	(non-dimensional)	By calculation
Bilirubin (total)	µmol/L plasma	KONELAB 30i Thermo Fisher Scientific 63303 Dreieich Germany
Cholesterol (total)	mmol/L plasma	
Creatinine	µmol/L plasma	
Glucose	mmol/L plasma	
Phosphate	mmol/L plasma	
Protein (total)	g/L plasma	
Urea (in blood)	mmol/L plasma	
Triglycerides	mmol/L plasma	
Calcium	mmol/L plasma	
Chloride	mmol/L plasma	
Potassium	mmol/L plasma	
Sodium	mmol/L plasma	
Alanine aminotransferase (ALAT)	U/L plasma	
Alkaline phosphatase (aP)	U/L plasma	
Aspartate aminotransferase (ASAT)	U/L plasma	
Lactate dehydrogenase (LDH)	U/L plasma	
Creatine kinase (CK)	U/L plasma	
Gamma-glutamyltransferase (Gamma-GT)	U/L plasma	

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3.8.7.4 Analysis of acute phase proteins

Blood samples were obtained as follows:

- On test day 4: The first 5 surviving main study animals per sex and group and all recovery animals (n = 10 per group).
- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group).

In order to obtain approximately 4 × 75 µL serum per animal and sampling time, approx. 0.7 mL whole blood per animal and sampling time were collected in serum separator tubes (Sarstedt AG & Co., Germany). The blood samples were allowed to clot at room temperature for at least 30 minutes, and centrifuged afterwards in order to obtain serum. Immediately after centrifugation, the serum was divided into aliquots and frozen at -20°C ±2°C until analysis at (b) (4) using commercial ELISA test kits purchased from Abcam PLC, Cambridge, United Kingdom (see text table below) and a Tecan Sunrise microplate reader (Tecan Deutschland GmbH, 74564 Crailsheim, Germany).

Text table 3-11: Parameters of acute phase protein analysis

Acute phase protein	Matrix	Sample volume	Number of aliquots (aliquot volume)	Storage temperature	Method
Alpha1-acid glycoprotein	Serum	150 µL	2 (75 µL)	-20°C ±2°C	Rat Alpha 1 Acid Glycoprotein / AGP ELISA Kit (ab157729, lot no. GR3235007-3)
Alpha2 macroglobulin	Serum	150 µL	2 (75 µL)	-20°C ±2°C	Rat alpha 2 Macroglobulin ELISA Kit (ab157730, lot nos. GR3322797-1, GR3322797-3, and GR3322797-4)

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3.8.7.5 Cytokine analysis

Blood samples for cytokine analysis were taken from the femoral vein catheter of all satellite animals at the times given in the text table below.

Text table 3-12: Blood sampling schedule for cytokine analysis

Test day	Sampling time relative to dosing	Animal numbers of satellite animals used							Number of samples/ aliquots
		Group 1[#]	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	
1	Prior to 1st dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
1	6 h post 1st dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
8	Prior to 2nd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
8	6 h post 2nd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240	241 to 246	247 to 252	42/84
10	48 h post 2rd dosing						241 to 246		6/12
15	Prior to 3rd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240		247 to 252	36/72
15	6 h post 3rd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240		247 to 252	36/72
17	48 h post 3rd dosing	211 to 216	217 to 222	223 to 228	229 to 234	235 to 240		247 to 252	36/72
								Total number of samples / aliquots:	**282/564**

[#] Blood sampling from the female animal no. 215 was performed by means of retrobulbar vein puncture (refer to Section 2.8 and Section 3.1).

Sufficient whole blood was collected from the animals in order to obtain at least 2×75 µL serum per animal and sampling time. The serum samples were frozen, stored and analysed as given in Text table 3-15 below.

Text table 3-13: Parameters of cytokine analysis

Cytokine	Matrix	LLOQ [pg/mL]	Sample volume	Number of aliquots (aliquot volume)	Storage temperature	Method
IFN-γ TNF-α IL-1-β IL-6 IL-10	Serum	4.0 7.1 12.6 3.0 9.9	150 µL	2 (75 µL)	-20°C ± 2°C	Cytometric bead array (ProcartaPlex) using a Cytomics FC 500 flow cytometer (Beckman Coulter GmbH, 47704 Krefeld, Germany)

LLOQ lower limit of quantification

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3.8.7.6 Urinalysis

Urine samples were collected from animals at the following time points:

- At main study termination (on the day of dissection): All main study animals (n = 10 per group).
- At the end of the recovery period (on the day of dissection): All recovery animals (n = 5 per group).

The urine was collected in a URIMAX funnel cage for 16 hours. The collection of urine was terminated immediately prior to the blood withdrawals for haematological and clinical chemistry examinations. The parameters measured and the methods used are given in the text table below.

Text table 3-14: Urinary parameters

Parameter	Unit	Instrument
Volume	mL	Graduated vessel
pH	n/a	Digital pH meter (type WTW InoLab pH 720)
Specific gravity	g/mL	Kern Refractometer (type ORA 2PA), sample compared with water (nominal value of 1.000)

In addition, the tests given in the text table below were performed using qualitative indicators (Combur 9® Test, Roche Diagnostics GmbH, 68305 Mannheim, Germany) of analyte concentration:

Text table 3-15: Analytes of qualitative urinalysis

Parameter	Reporting convention					
	Unit	Semi-quantitative determination level				
Protein	g/L	neg	0.3	1	5	
Glucose	mmol/L	normal	2.8	5.5	17	55
Bilirubin	-	neg	+	+ +	+ + +	
Urobilinogen	µmol/L	normal	17	70	140	200
Ketones	-	neg	+	+ +	+ + +	
Haemoglobin (Hb, approx. values)	ery/µL	neg	10	25	50	250
Nitrite	-	neg	pos			

neg = negative
pos = positive
ery = erythrocyte count

\+ 'Small amount' of analyte
+ + 'Moderate amount' of analyte
+ + + 'Large amount' of analyte

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A microscopic examination of urine samples was carried out by centrifuging samples and spreading the resulting deposit on a microscope slide. The deposit was examined for the presence of the following parameters:

- Epithelial cells
- Leucocytes
- Erythrocytes
- Organisms
- Further constituents (i.e. sperm, casts)
- Crystalluria

The frequency of the above parameters in the centrifugal deposit was recorded as follows:

0	None found in any field examined
+	Few in some fields examined
+ +	Few in all fields examined
+ + +	Many in all fields examined

The colour and the turbidity of the urine were examined visually.

3.8.8 Blood sampling for dose exposure

In order to obtain serum samples for dose exposure examination (10 aliquots of approximately 100 µL each per animal), blood was withdrawn from the retrobulbar venous plexus under isoflurane anaesthesia from animals fasted overnight as follows:

- At main study termination (on the day of dissection): All main study animals.
- At the end of the recovery period (on the day of dissection): All recovery animals

In total 209 samples (2074 aliquots) were collected. No blood sample for dose exposure examination could be collected from the male animal no. 130 (group 6) as the animal died during blood withdrawal on test day 17 such that only the samples for the laboratory examinations could be obtained. Further, for a few animals, the blood volume sampled was not sufficient for 10 aliquots of 100 µL serum each but yielded only 7 to 9 aliquots.

After collection of sufficient whole blood in serum separator tubes (Sarstedt®, Germany), the blood samples were allowed to clot for at least 30 minutes before centrifugation. Immediately after centrifugation, the serum was frozen and stored at -80°C ±8°C until shipment for analysis.

The samples were labelled with the study number, species, animal number, type of sample, purpose (dose exposure), aliquot no., group number, test day and date.

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Following advance notice by e-mail (to: (b) (6) and (b) (6)), the dose exposure samples were dispatched on dry ice via courier as given in the text table below.

Text table 3-16: Shipping schedule of dose exposure samples

Shipped by (b) (4)	Delivered to the Sponsor	Animals	Aliquots included	Consignee
06 Apr 2020	07 Apr 2020	Groups 1, 2, 4, 6 Main Study N = 80	Aliquots 1 to 10# (n = 790)	BioNTech RNA Pharmaceuticals (b) (6) An der Goldgrube 12 55131 Mainz Germany
09 Apr 2020	09 Apr 2020	Groups 3, 5##, 7 Main study N = 60	Aliquots 1 to 10# (n = 586)	
30 Apr 2020	30 Apr 2020	Groups 1 to 7 Recovery N = 70	Aliquots 1 to 10# (n = 698)	

As far as available. For a few animals, less than 10 aliquots (but at least 7 aliquots) per sampling were available as the blood volume sampled was not sufficient to yield 10 aliquots of 100 µL serum each.

No blood sample could be collected from the male animal no. 130 (group 6) as the animal died during blood withdrawal.

The samples were analysed for immunogenicity of the test items by BioNTech SE, Germany, under the responsibility of the Sponsor. An analytical report was forwarded to (b) (4) (see Section 4.12 and Appendix 4).

3.8.9 Ophthalmological and auditory examinations

Examinations were performed on all main study and recovery animals before first dosing and at the end of the dosing period (groups 1 to 5 and 7: test day 16, group 6: test day 9), and for all recovery animals at the end of the recovery period (groups 1 to 5 and 7: test day 37, group 6: test day 30).

The eyes were examined with a HEINE ophthalmoscope. After examination of the pupillary reflex, mydriasis was produced by instillation of STULLN® eye drops (Ankerpharm GmbH, 07407 Rudolstadt, Germany) onto the cornea.

The following ocular structures were examined:

- Adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva
- Cornea, anterior chamber
- Lens, vitreous body, fundus (retina, optic disc)

The auditory acuity was checked with a simple noise test.

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3.8.10 Pathology and histopathology

3.8.10.1 Necropsy

For groups 1 to 5, and 7, necropsy was scheduled for test day 17 (approximately 48 hours after the last administration) for the main study animals and for test day 38 for all animals allocated to the recovery period.

For group 6 necropsy was scheduled for test day 10 (approximately 48 hours after the last administration) for the main study animals and for test day 31 for all animals allocated to the recovery period.

The animals were sacrificed and dissected following a randomization scheme.

The animals were euthanized by carbon dioxide (CO_2) inhalation, exsanguinated by cutting the aorta abdominalis, weighed, dissected, and inspected macroscopically under the direction of a pathologist.

All superficial tissues were examined visually and by palpation. The cranial roof was removed to allow observation of the brain, pituitary gland and cranial nerves. After ventral midline incision and skin reflection, all subcutaneous tissues were examined. The condition of the thoracic viscera was noted with due attention to the thymus, lymph nodes and the heart.

The abdominal viscera were examined before and after removal; the urinary bladder was examined externally and by palpation. The gastro-intestinal tract was examined as a whole, and stomach and caecum were incised and examined. The lungs were removed and all pleural surfaces were examined under suitable illumination. The liver and the kidneys were examined. Any abnormalities in the appearance and size of the gonads, adrenal glands, uterus, intraabdominal lymph nodes and accessory reproductive organs were recorded.

None of the satellite animals was dissected and examined macroscopically as none of these animals had deceased or was prematurely sacrificed.

The erroneously administered animals (see Section 3.7) were not dissected.

The animals no. 76 and no. 130 which died during blood withdrawal closely before the pending terminal sacrifice on test day 17 were dissected immediately after the incident.

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The organs listed in the text table below were weighed before fixation.

Text table 3-17: Weighed organs

Weighed organs	
Adrenal gland (2)	Ovary (2)
Brain	Pituitary gland
Epididymis (2)	Prostate
Heart	Spleen
Kidney (2)	Testicle (2)
Liver	Thymus
Lungs	Thyroid (1, including parathyroids)
Lymph nodes (one cervical, one mesenteric)	

The paired organs were identified as left or right and weighed individually.

Organ/body weight ratios were calculated (using the body weight at autopsy obtained after exsanguination at necropsy) and are presented as relative organ weights (in g/kg b.w.).

3.8.10.2 Organ preservation

The organs or parts of organs of all animals listed in the text table on the following page were fixed in 7% neutral buffered formalin, except for the eyes which were fixed in Davidson's solution, and the testes which were fixed in modified Davidson's solution for optimum fixation.

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Text table 3-18: Tissues collected for preservation

Tissues preserved for histopathology	
Adrenal gland *(2)*	Mammary gland
# Animal ID	Muscle *(skeletal, leg)*
Aorta abdominalis	Nerve *(sciatic)*
# Body cavity, nasal	# Nerve *(tibial, 2)*
Bone *(os femoris with joint)*	Oesophagus
Bone *(sternum)*	Ovary *(2)*
Bone marrow *(os femoris)*	Oviducts *(2)*
Brain *(cerebrum, cerebellum, brain stem)*	Pancreas
Caecum	Parathyroids
# Clitoral gland *(2)*	Pituitary
Epididymis *(2)*	# Preputial gland *(2)*
Eye with optic nerve *(2)*	Prostate
# Ganglion, dorsal root, lumbar	Salivary glands *(mandibular, parotid, sublingual)*
Gut-associated lymphoid tissue	
Harderian gland *(2)*	Seminal vesicle *(2)*
Heart *(left and right ventricle, septum)*	Skin *(left flank*)
Injection sites 1 and 2	Spinal cord *(3 sections)*
Intestine, small *(duodenum, jejunum, ileum, Swiss roll method)*	Spleen
	Stomach
Intestine, large *(colon, rectum)*	Testicle *(2)*
Kidney and ureter *(2)*	Thymus
Lacrimal gland *(extraorbital)*	Thyroid *(2)*
# Larynx	Tongue *(including base)*
Liver *(2 lobes)*	Trachea
Lungs *(with mainstem bronchi and bronchioles)*	# Ureter *(2)*
Lymph node *(1, cervical)*	Urinary bladder
Lymph node *(1, mesenteric)*	Uterus *(including cervix)*
# Lymph node *(2, mandibular)*	Vagina
Lymph node *(1, draining administration site: iliac)*	# Zymbal's gland *(2)*

The tissues marked with the hash sign ('#') were preserved, but not further processed. They may be evaluated if requested by the Sponsor. So far, no evaluation was performed by (b) (4).

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3.8.10.3 Bone marrow

During dissection, fresh bone marrow was obtained from the os femoris (3 air-dried smears per animal) of the first 5 main study animals per sex and group, and of all recovery animals and stained as given in the text table below.

Text table 3-19: Staining of bone marrow smears

Dissection	Group	Number of stainings	
		Pappenheim	Giemsa
Main study (5 animals per sex and group)	Groups 1, 2 and 4	1	0
	Group 6	1	0
	Groups 3, 5 and 7	1	2
Recovery (5 animals per sex and group)	Groups 1, 2 and 4	1	2
	Group 6	1	2
	Groups 3, 5 and 7	1	2

The stained bone marrow smears may be evaluated, if requested by the Sponsor (details are to be stated in a Study Plan amendment). So far, no evaluation of bone marrow smears was performed by (b) (4).

3.8.10.4 Histopathology

The organs listed in Section 3.8.10.2, with the exception of the organs marked with the hash sign ('#'), of all main study and recovery animals of all groups were examined histopathologically after preparation of paraffin sections and haematoxylin-eosin staining.

Parathyroids cannot always be identified macroscopically. They were examined microscopically if in the plane of section and in cases they were noted as grossly enlarged.

Blood smears prepared for haematological examination (see Section 3.8.7.1) are available for a possible examination of pathological changes but may be examined and evaluated only depending on necropsy findings and upon agreement with the Sponsor. So far, no examination was performed.

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3.8.11 Statistics

All toxicology and pathology data were captured, as far as possible, using the departmental computerized systems (Provantis® Integrated preclinical software, version 10.2, Instem LSS Ltd., Stone, Staffordshire ST15 0SD, United Kingdom). Raw data not fully compatible with the computerized systems were maintained on paper according to appropriate SOPs.

The test item-treated groups 2 to 5 and 7 were compared to the control group 1. The test item-treated group 6 was compared to the control group 1 as far as possible. Due to the earlier sacrifice of the animals of group 6 (main study animals: test day 10, recovery animals: test day 31), the following parameters of group 6 were statistically compared to the control group on test day 4 only:

- Haematology and coagulation
- Clinical chemistry
- Urinalysis
- Cytokines
- Acute phase proteins
- Relative and absolute organ weights

The statistical methods described in the text table below were used for the data captured with the Provantis system.

Text table 3-20: Statistical methods

Statistical method	Parameters analysed
Multiple t-test based on DUNNETT, C. W. New tables for multiple Comparisons with a control *Biometrics,* 482-491 (Sept 1964)	Body weight / Food consumption / Haematology and coagulation / Clinical chemistry / Acute phase proteins / Urinalysis / Cytokines / Relative and absolute organ weights ($p \leq 0.05$ and $p \leq 0.01$)
Exact test of R. A. FISHER (if applicable)	Histopathology ($p \leq 0.05$)

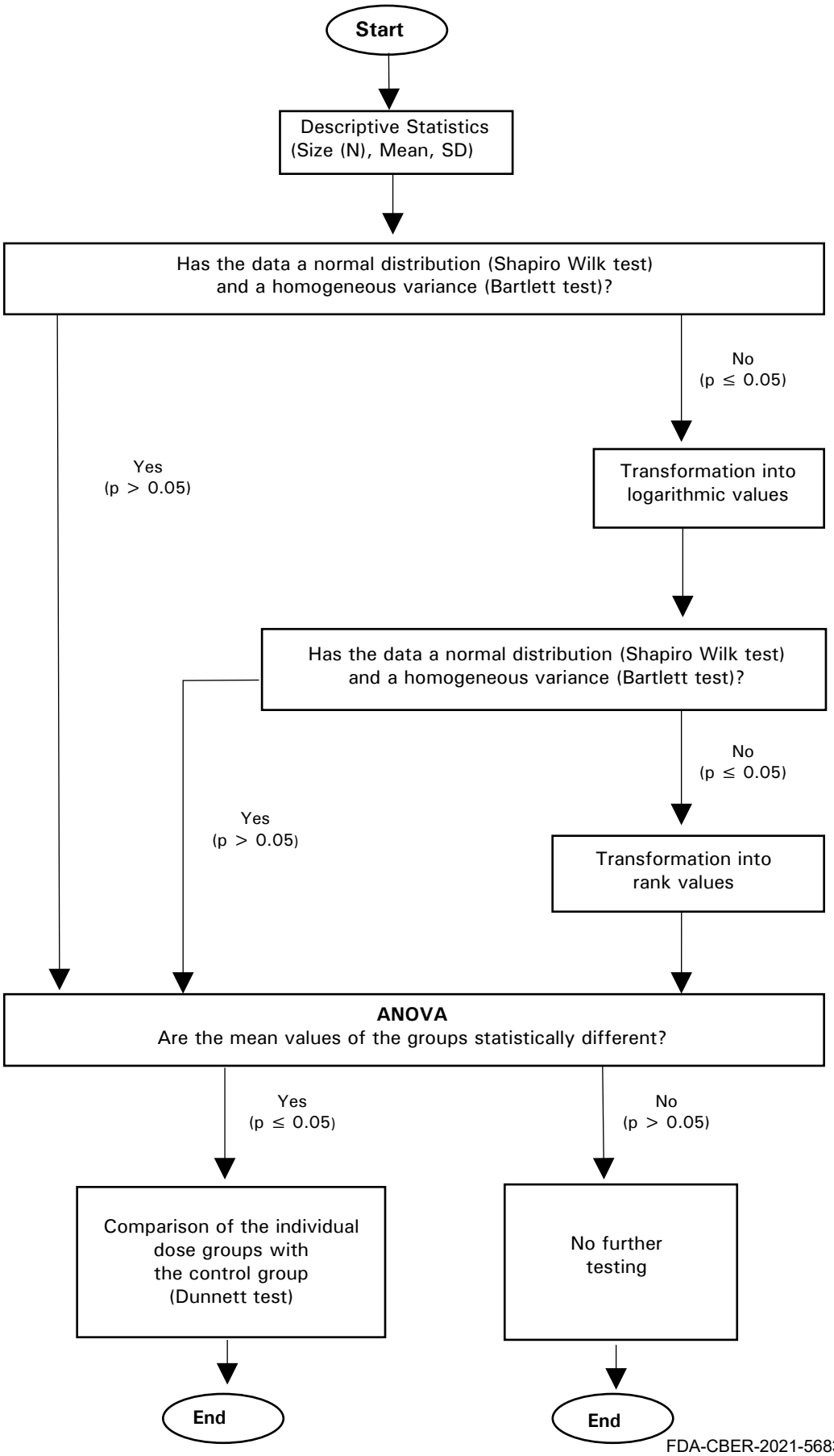
The following settings were used for the statistical evaluation of the parametrical values captured by Provantis (see flow chart of decision tree on page 59):

Homogeneity of variances and normality of distribution were tested using BARTLETT's test and SHAPIRO-WILK's test. In case of heterogeneity and/or non-normality of distribution, stepwise transformation of the values into logarithmic or rank values was performed prior to ANOVA. If the ANOVA yielded a significant effect ($p \leq 0.05$), intergroup comparisons with the control group were made by DUNNETT's test (see above).

The statistical procedures were used for all data. Statistically significantly different data are indicated in the tables of Section 5 ('TABLES') of the report.

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Flow Chart of Decision Tree of ANOVA and Dunnett's Test Calculation



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4. RESULTS

4.1 Local tolerance

BNT162a1 - Groups 2 and 3

Treatment period

Very slight to moderate oedema were noted for all animals following the 1st, 2nd, and/or 3rd injection of **10** or **30 µg BNT162a1/animal** on test days 1, 8, and 15.

Male and female animals treated with **10** or **30 µg BNT162a1/animal** (group 2) revealed very slight to well-defined erythema following the 1st or 2nd injection (up to 96 h after administration), and/or the 3rd injection (up to 48 h after administration). In addition, all male and female animals of administered **30 µg BNT162a1/animal** revealed a scabby skin at the injection site at 96 h after the 1st administration (on test day 4, see column 'F' in Table 1-2). Severe erythema (grade 4) for 5 of 15 male animals and 4 of 15 female animals treated with **10 µg BNT162a1/animal** (group 3) was noted on test day 14 (144 h after the 2nd administration on test day 8), but was resolved prior to the 3rd injection.

Further, the injection site appeared to be painful for 4 of 15 male animals and 12 of 15 female animals treated with the high dose of **30 µg BNT162a1/animal** on test day 9 (for one male animal also on test day 10) following administration of the 2nd dose on test day 8.

On test day 14 (day before 3rd administration), eschar formation was observed at the injection site for 5 male and 6 female animals treated with of **30 µg BNT162a1/animal** (group 2). Therefore, on test day 15, the male animals nos. 32, 34, 37, 39 and 42, and the female animal no. 60 were dosed intramuscularly in the left hind leg instead of the right hind leg as during the previous administrations. In the affected animals, both administration sites were fixed at necropsy and processed for histological examinations.

The macroscopic inspection at necropsy revealed an indurated and/or thickened injection site for all main study animals treated with **30 µg BNT162a1/animal** and for the majority of animals treated with **10 µg BNT162a1/animal**. For a few animals, an incrustation was noted at the injection site (high dose: 2 males and 2 females, low dose: one male).

All findings described above are considered to be test item-related based on the increases incidence and/or severity observed compared with buffer controls. The findings are considered to be related to immune responses at the site of vaccine administration.

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Recovery period

Very slight to slight oedema were still noted for nearly all animals previously treated with **10** or **30 µg BNT162a1/animal** during the early part of the recovery period (following the 3rd injection on test day 15). No dose-dependency was observed. All oedema had subsided as of test day 29 (i.e. 336 h after the last administration) at the latest.

All male and female animals administered **30 µg BNT162a1/animal** revealed severe erythema (grade 4) at 96 h after the last test item injection (test day 19). In the majority of animals, this skin reddening had subsided at 240 h p.a. (test day 25). Only 2 male and 2 female animals revealed erythema up to 432 h p.a. (test day 33). The skin reddening is considered to be test item-related.

At the end of the recovery, any local skin reactions with regard to erythema, oedema, indurations, and/or hardenings had subsided.

No abnormalities were noted at the injection site(s) of any animal at macroscopic inspection at necropsy at the end of the recovery period.

BNT162b1 - Groups 4 and 5

Treatment period

Very slight (mostly) to moderate (rarely) oedema were noted for all animals following the 1st, 2nd, and/or 3rd injection of **30** or **100 µg BNT162b1/animal** on test days 1, 8, and/or 15. In the high dose group 5, the two injection sites were occasionally affected to a different degree. In addition, individual animals of the low dose group treated with **30 µg BNT162b1/animal** (group 4) also revealed very slight erythema, observed only at 24 h following injection. No dose-dependency was observed for the skin reactions. All effects had subsided by 96 h p.a. after each of the first two injections.

Severe erythema (grade 4) for 3 female animals (nos. 136, 137, and 146) treated with **100 µg BNT162b1/animal** (group 5) was observed only on test day 14 (144 h after the 2nd administration on test day 8) and is considered test item related. This observation was no longer present prior to the 3rd injection.

An indurated and/or thickened injection site was noted for 7 male and 6 female animals per group and dose level for the main study animals treated with **30** or **100 µg BNT162b1/animal** at macroscopic inspection at necropsy.

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Recovery period

Very slight (mostly) to well-defined (rarely) oedema for nearly all animals administered **30 µg BNT162b1/animal**, and very slight (mostly) to moderate (rarely) oedema for nearly all animals administered **100 µg BNT162b1/animal** were still noted during the early part of the recovery period (following the 3rd injection on test day 15). All oedema had subsided by test day 35 (i.e. 480 h after the last administration).

No abnormalities were noted at the injection site(s) of any animal at macroscopic inspection at necropsy at the end of the recovery period.

BNT162c1 - Group 6

Treatment period

Very slight (mostly) to moderate (rarely) oedema were noted for all animals following the 1st and/or 2nd injection of **30 µg BNT162c1/animal** on test days 1 and/or 8. In addition, individual male and female animals also revealed very slight erythema, observed only at 96 h after the 1st injection. All effects had subsided by 144 h p.a. after of the first injection (test day 7).

The macroscopic inspection at necropsy revealed an indurated and/or thickened injection site for all male and female main study animals treated with **30 µg BNT162c1/animal**. In addition, an incrustation was noted at injection site of one male and one female animal.

Recovery period

Very slight (mostly) to severe (very rarely) oedema were still noted for nearly all animals previously treated with **30 µg BNT162c1/animal** during the early recovery period (following the 2nd injection on test day 8). In addition, individual animals also revealed a severe erythema, observed only at 144 h following injection (test day 14). In nearly all male and female animals, all local skin reactions had subsided until test day 16 (i.e. 192 h after the last administration). Only one male animal (no. 162) still presented with reddened skin (scored as severe "erythema" up to test day 24, followed by very slight slight degree up to test day 30) accompanied by an incrusted wound and scar tissue formation. This finding is attributed to test article-associated inflammation at the injection site.

One male animal (no. 179) revealed eschar formation in a skin area on the right leg that was near to but outside the location used for test item injection on test days 18 to 24. This finding is not considered to be related to the test item administration but to be related to the shaving procedure in advance of the start of treatment.

No abnormalities were noted at the injection site(s) at macroscopic inspection at necropsy at the end of the recovery period.

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BNT162b2 - Group 7

Treatment period

Very slight to severe (very rarely) oedema were noted for all animals following the 1st, 2nd, and/or 3rd injection of **100 µg BNT162b2/animal** on test days 1, 8, and/or 15. All oedema noted after the 1st or 2nd injection had subsided by 96 h p.a. after the respective administration.

In addition, a few female animals also revealed very slight erythema following 24 to 96 h following the 1st or 2nd injection. For individual male and female animals, skin reddening (scored as "severe" erythema) was observed only at 144 h after the 2nd injection, but was resolved prior to the 3rd injection.

The macroscopic inspection at necropsy revealed an indurated and/or thickened injection site for 7 of 10 male and 9 of 10 female main study animals treated with **100 µg BNT162b2/animal**.

Recovery period

Very slight (mostly) to moderate (rarely) oedema were still noted for all animals previously treated with **100 µg BNT162b2/animal** during the early part of the recovery period (following the 3rd injection on test day 15). All local skin reactions had subsided by 336 h p.a. (test day 29).

No abnormalities were noted at the injection site(s) at macroscopic inspection at necropsy at the end of the recovery period.

Histopathological examination of injection sites

Treatment period

The histopathological examination revealed test item-related injection site findings in all groups, characterized by mostly moderate inflammation (up to marked) in males and moderate inflammation in females. The most severe findings were noted consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate oedema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. There were no notable injection site findings in control-item administered groups. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac).

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Recovery period

Microscopic findings noted at the injection sites were partially or fully resolved at the end of the 3-week recovery phase. A few inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals.

Microscopic injection site findings correlated with macroscopic findings of thickening, induration, and incrustation.

General observations of local intolerance reactions are given in Table 1-1 (Local tolerance - General observations) and observations of erythema, oedema, indurations, and/or hardenings are listed in Table 1-2 (Local tolerance - Erythema, Oedema, Induration, Hardening).

For detailed listings of histopathological findings at the injection sites, refer to Text table 4-24 (10 or 30 µg BNT162a1/animal, groups 2 and 3), Text table 4-25 (30 or 100 µg BNT162b1/animal, groups 4 and 5), and Text table 4-26 (30 µg BNT162c1/animal, group 6, and 100 µg BNT162b2/animal, group 7).

4.2 Clinical signs

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment and recovery period

None of the male and female animals treated intramuscularly with **10** or **30 µg BNT162a1/animal** (groups 3 and 2), **30** or **100 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** (group 6) on test days 1 and 8 (2 administrations) revealed any test item-related systemic changes in behaviour, external appearance, or consistency of faeces.

A summary of clinical observations is given in Table 2-1 (Clinical Signs - Summary), the individual observations are listed in Table 2-2 (Clinical Signs - Individual Data).

4.3 Mortality

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment and recovery period

No test item-related deaths were noted for any treatment.

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The female animal no. 76 treated with **30 µg BNT162a1/animal** (group 3) and the male animal no. 130 treated with **30 µg BNT162b1/animal** (group 5) died during the blood sampling for dose exposure examination on test day 17 (day of dissection). However, the deaths of these animals are not considered to be test item-related but to be related to the stress caused by the technical procedure of blood withdrawal from the retrobulbar venous plexus under isoflurane anaesthesia after the animals had been fasted overnight.

The macroscopic inspection at necropsy did not reveal any abnormalities for animal no. 76. An enlarged spleen, enlarged adrenal glands, and an enlarged iliac lymph node were noted for animal no. 130. The absolute weight of the spleen was increased by approx. 21% compared to the mean value of the control group. However, these findings are not considered to be sufficient to causally explain the animal's premature death. In summary, the histopathological examination did not reveal a clear cause of death for any of the deceased animals.

As the animals died during terminal anaesthesia, closely before the pending sacrifice, and were dissected immediately after death, the organ weight data from these animals were included into statistical analysis as scheduled.

4.4 Body weight

Mean values per group and individual data of body weight, body weight gain, and body weight at autopsy are listed in Table 3-1 (Body Weight - Summary), Table 3-2 (Body Weight - Individual Data), Table 3-3 (Body Weight Gain-Summary), Table 3-4 (Body Weight Gain - Individual Data), and Table 3-5 (Body Weight at Autopsy).

The mean body weight is plotted in Figure 1-1 (male animals) and Figure 1-2 (female animals) on the following page.

The mean body weight gain for the treatment period from test day 1 to test day 9 (group 6) or test day 16 (groups 1 to 5 and 7) and for the recovery period from test day 10 to test day 30 (group 6) or test day 16 to test day 37 is shown graphically in Figure 1-3 (male animals) and Figure 1-4 (female animals) on page 72.

The body weight at autopsy at terminal sacrifice (test day 9 for group 6, test day 16 for groups 1 to 5 and 7) and at recovery sacrifice (test day 30 for group 6, test day 37 for groups 1 to 5 and 7) is shown graphically in Figure 1-5 (male animals) and Figure 1-6 (female animals) on page 73.

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BNT162a1 - Groups 2 and 3

Treatment period

The body weight of the male animals treated with the high dose of **30 µg BNT162a1/animal** (group 2) on test days 1, 8, and 15 was reduced by up to 16.7% in comparison to the control animals on test days 2, 8/9, and 15/16 (statistically significant at $p \leq 0.01$ as of test day 2). The body weight gain was reduced accordingly by 22 percentage points compared to the control group for the period from test day 1 to test day 16. However, the lowered body weight gain over the whole treatment period is mainly due to the weight loss observed on each day after an administration day. The slope of weight gain increase was the same each time between the day after administration until next dosing compared to the control group. In summary, the absolute body weight was affected, but the body weight gain between dosing was not. Consistent with the lower overall body weight gain, the body weight at autopsy was approx. 17% lower than in the control group on test day 17.

The female animals treated with **30 µg BNT162a1/animal** revealed a slight, but statistically significant (at $p \leq 0.01$ or $p \leq 0.05$) reduction of body weights by up to 7% compared to the control group on test days 9 and 16 (on the respective day after the administrations on test days 8 and 15 in each case). Although changes were not always statistically significant for the female animals, the trend is the same as for the male animals. The body weight gain was approx. 7 percentage points lower than in the control group for the period from test day 1 to test day 16. The body weight at terminal sacrifice (test day 17) was reduced by only approx. 5% compared to the control group indicating some weight re-gain by the end of the dosing period.

The test item-related body weight changes noted for the treatment with **30 µg BNT162a1/animal** are summarised in the text table below.

Text table 4-1: Test item-related body weight changes for BNT162a1

Test item-related changes in mean body weight compared to the control group [%] (refer to Table 3-1)		
Test day	**Group 2: 30 µg BNT162a1/animal**	
	Males	**Females**
2	-6.9**	-4.5
8	-5.6**	None
9	-13.1**	-6.5*
15	-11.5**	-2.6
16	-16.7**	-7.0**

None No test item-related change.

* / ** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

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A body weight increase of up to 19.2% noted for the male animals administered **10 µg BNT162a1/animal** (group 3) in comparison to the control animals on test days 1, 2, and 8 (statistically significant at $p \leq 0.01$) was due to their older age (+6 days) at start of the study (staggered start, refer to Section 2.7). However, the body weight gain from test day 1 to test day 16 was *decreased* compared to the control animals, resulting in slightly lower body weights than in the control group on test day 16. The body weight gain was decreased by approx. 25 percentage points compared to the control group for the period from test day 1 to test day 16.

The female animals treated with **10 µg BNT162a1/animal** (group 3) on test days 1, 8, and 15 revealed a slight decrease of body weight by up to 5.2% in comparison to the control animals on test days 9, 15 and 16. Their body weight gain from test day 1 to test day 16 was only approx. 6 percentage points lower compared to the control group.

The body weight at autopsy was not affected for the male animals and only marginally decreased for the female animals administered **10 µg BNT162a1/animal** (group 3) compared to the control group at terminal sacrifice on test day 17. However, due to the older age slightly higher body weights than in the control group were expected. Therefore, a slight effect on the body weight and the body weight gain due to the treatment with **10 µg BNT162a1/animal** cannot be ruled out completely.

Recovery period

No noteworthy changes were noted for the body weights of the male and female animals previously treated with **10** or **30 µg BNT162a1/animal** (groups 3 and 2) in comparison to the control animals at the end of the recovery period. The body weight gain of the animals was up to approx. 16 percentage points higher compared to the control group for the period from test day 16 to test day 37.

BNT162b1 - Groups 4 and 5

Treatment period

The body weight of the male animals treated with **30 µg BNT162b1/animal** on test days 1, 8, and 15 (group 4) was reduced by up to 8.8% in comparison to the control animals on test day 16 (statistically significant at $p \leq 0.01$). The body weight gain was reduced accordingly by 12 percentage points compared to the control group for the period from test day 1 to test day 16. The body weight at autopsy was 7.3% lower than in the control group on test day 17.

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No noteworthy differences were noted for the body weight, the body weight gain, and the body weight at autopsy between the female animals treated with **30 µg BNT162b1/animal** (group 4) and the control group until the end of the treatment period.

Up to test day 8, the male animals treated with **100 µg BNT162b1/animal** on test days 1, 8, and 15 (group 5) revealed *higher* body weights than the control group animals due to their older age (+6 days compared to the control animals), but a body weight decrease by up to 9.3% compared to the control group as of test day 9 (statistically significant at $p \leq 0.01$ on test days 9 and 16). The body weight gain was reduced by approx. 31 percentage points compared to the control group for the period from test day 1 to test day 16. The body weight at autopsy was approx. 5% lower than in the control group on test day 17.

The female animals treated with **100 µg BNT162b1/animal** revealed a statistically significant (at $p \leq 0.05$) reduction of body weight by 6.1% compared to the control group on test day 9, but there were no noteworthy differences for the body weight, the body weight gain, and the body weight at autopsy in comparison to the control group on test day 17.

The body weight changes that are considered to be related to the treatment with **BNT162b1** are summarised in the text table below.

Text table 4-2: Test item-related body weight changes for BNT162b1

Test item-related changes in mean body weight compared to the control group [%] **(refer to Table 3-1)**				
Test day	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
2	-4.7**	None	None	-4.7
9	-6.5*	None	-6.6**	-6.1*
15	-5.1*	None	-2.4	None
16	-8.8**	None	-9.3**	-4.5

None No test item-related change.
* / ** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy changes were noted for the body weights of the male and female animals previously treated with **30** or **100 µg BNT162b1/animal** (groups 4 and 5) in comparison to the control animals at the end of the recovery period. The body weight gain of the animals was up to approx. 9 percentage points higher compared to the control group for the period from test day 16 to test day 37.

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BNT162c1 - Group 6

Treatment period

Up to test day 8, the male animals treated with **30 µg BNT162c1/animal** (group 6) revealed body weights that were up to 17% *higher* than in the control group due to their older age (+6 days compared to the control animals). On test day 9, a body weight reduction of 4.3% was noted compared to the control group (not statistically significant at $p \leq 0.01$ or $p \leq 0.05$). No body weight gain was noted for the period from test day 1 to test day 9 whereas the body weight gain in the control group was 21.34% for that period. The body weight at autopsy was approx. 17% lower compared to the control group's body weight at autopsy on test day 10 although the animals in group 6 and in the control group had a comparable age at sacrifice (group 6: 70 days, control group: 71 days).

The female animals treated with **30 µg BNT162c1/animal** revealed a statistically significant (at $p \leq 0.01$) reduction of body weight by 7.0% compared to the control group on test day 9. There was a marginal body weight gain of only approx. 1.5% for the period from test day 1 to test day 9. The body weight at autopsy was approx. 12% lower compared to the control group's body weight at autopsy on test day 10 (the females had the same age as the males, see above).

Recovery period

No noteworthy changes were noted for the body weights of the male and female animals previously treated with **30 µg BNT162c1/animal** in comparison to the control animals at the end of the recovery period. The body weight gain of the animals appeared to be higher compared to the control group for the period from test day 9 to test day 30 (not quantifiable due to the different time course).

BNT162b2 - Group 7

Treatment period

Up to test day 8, the male animals treated with **100 µg BNT162b2/animal** (group 7) revealed body weights that were up to 16% *higher* than in the control group due to their older age (+6 days compared to the control animals). A body weight reduction of up to 11.3% was noted compared to the control group on test days 9, 15, and 16 (statistically significant at $p \leq 0.01$ on test days 9 and 16). There was a body weight gain of only approx. 5% for the period from test day 1 to test day 16, which is approx. 32 percentage points lower compared to the control group. The body weight at autopsy was approx. 8% lower compared to the control group on test day 17.

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The female animals treated with **100 µg BNT162b2/animal** revealed a reduction of body weight by up to 6.8 % compared to the control group starting on test days 2 to 16 (statistically significant at $p \leq 0.01$ or $p \leq 0.05$ on test days 9 and 16). A body weight gain of approx. 6% was noted for the period from test day 1 to test day 16, being approx. 10 percentage points lower compared to the control group. No noteworthy difference was noted for the body weight at autopsy between the females treated with **100 µg BNT162b2/animal** and the females of the control group on test day 17.

Recovery period

No noteworthy changes were noted for the body weight, body weight gain, and body weight at autopsy of the male animals previously treated with **100 µg BNT162b2/animal** in comparison to the control animals at the end of the recovery period. The body weight of the female animals was consistently slightly lower compared to the control group, despite of their older age. The body gain from test day 16 to test day 37 was nearly identical to that of the control group. At the end of the recovery period, there was no noteworthy difference in body weight between the two groups.

Statistically significant differences observed for the body weight between any test item-treated group and the control group as listed in the text table below are not considered to be test item-related but to be coincidental changes.

Text table 4-3: Statistically significant body weight changes considered not test item-related

Body weight changes compared to the control group considered not test item-related (refer to Table 3-1)							
Group	**Test item no.#**	**Dose [µg/animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
3	1	10	m	1	+19.2	$p \leq 0.01$	A
				2	+12.7	$p \leq 0.01$	A
				8	+10.0	$p \leq 0.01$	A
5	3	100	m	1	+17.3	$p \leq 0.01$	A
6	5	30	m	1	+17.0	$p \leq 0.01$	A
				2	+9.1	$p \leq 0.01$	A
7	4	100	m	1	+16.0	$p \leq 0.01$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change is due to the older age of the animals.

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Figure 1-1 Body weight of male rats treated once weekly, mean values per group
Up to 3 administrations per animal (TD 1/8/15)

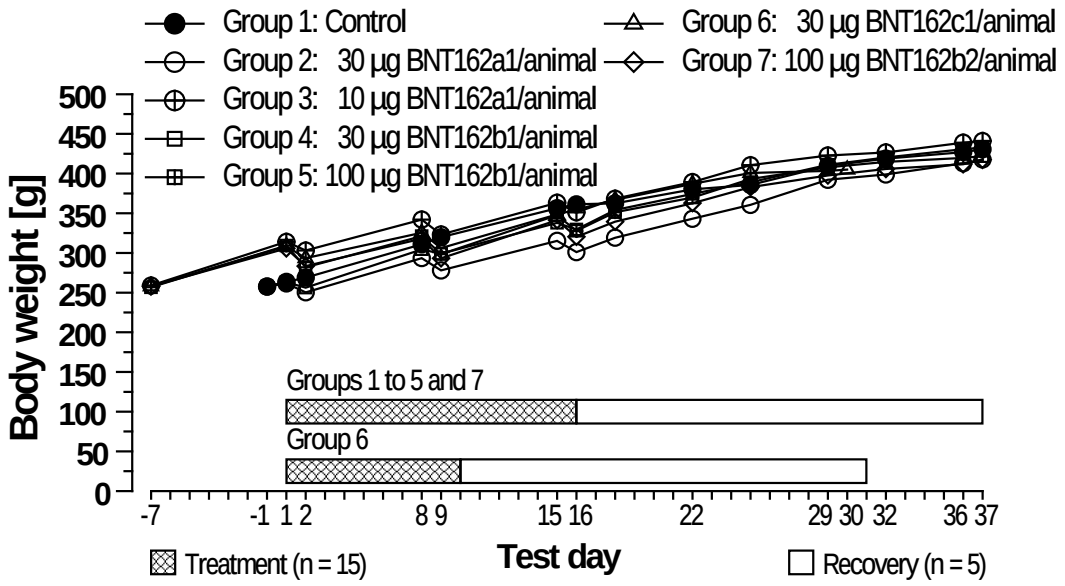
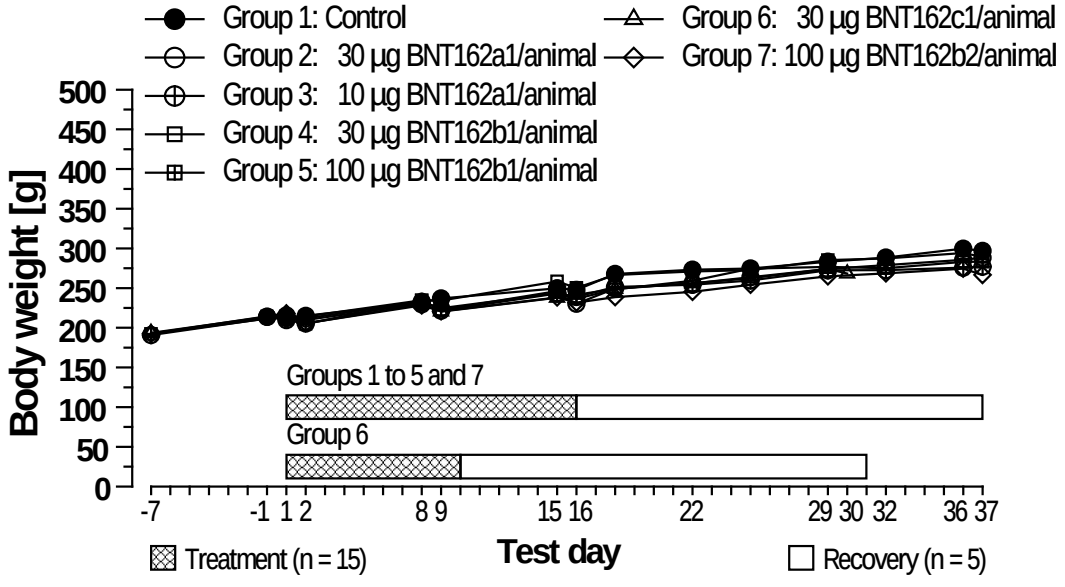


Figure 1-2 Body weight of female rats treated once weekly, mean values per group
Up to 3 administrations per animal (TD 1/8/15)



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Figure 1-3 Body weight gain of male rats treated once weekly, mean values per group and standard deviation

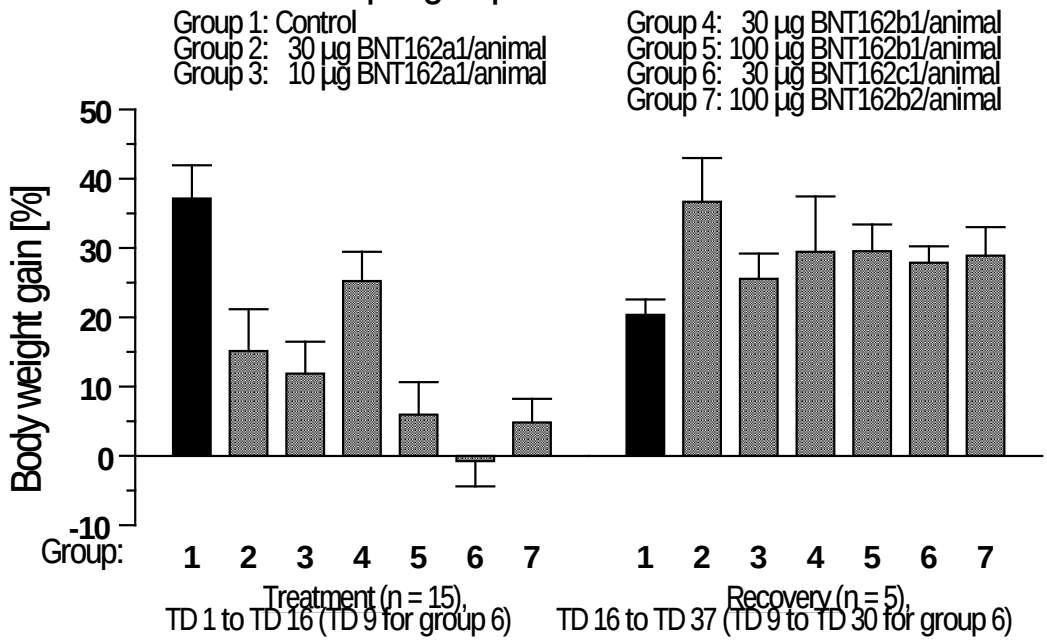
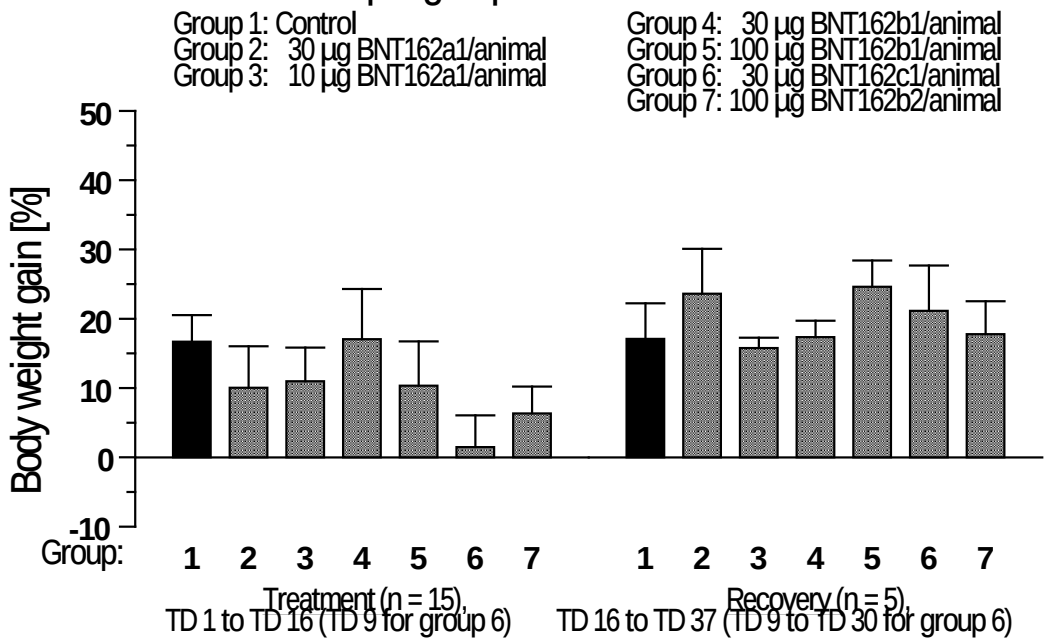


Figure 1-4 Body weight gain of female rats treated once weekly, mean values per group and standard deviation



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Figure 1-5 Body weight at autopsy, individual data -Males

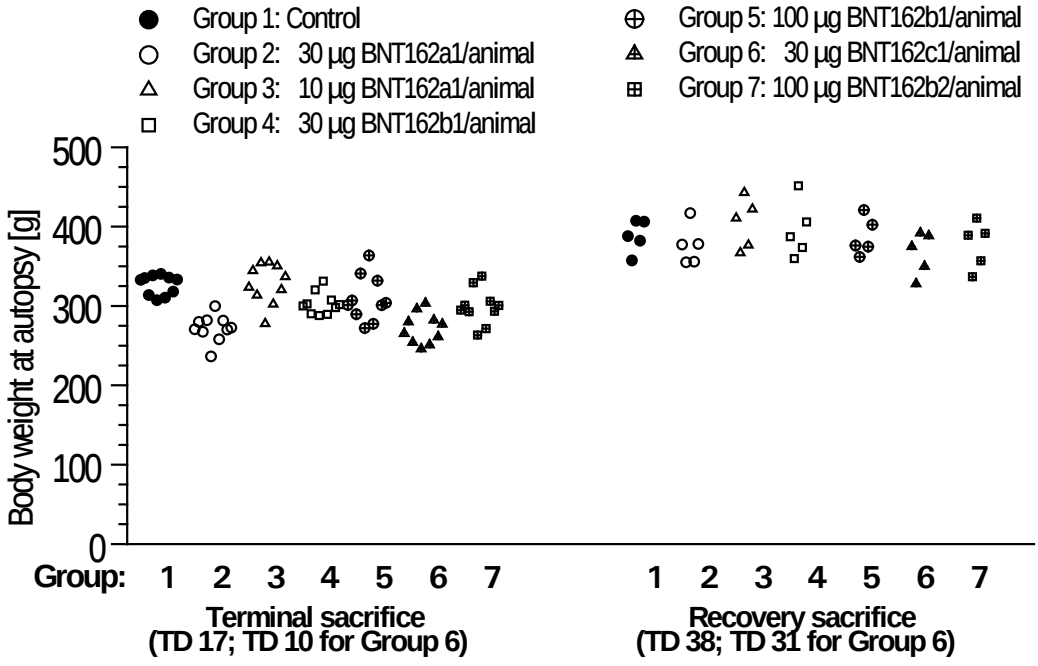
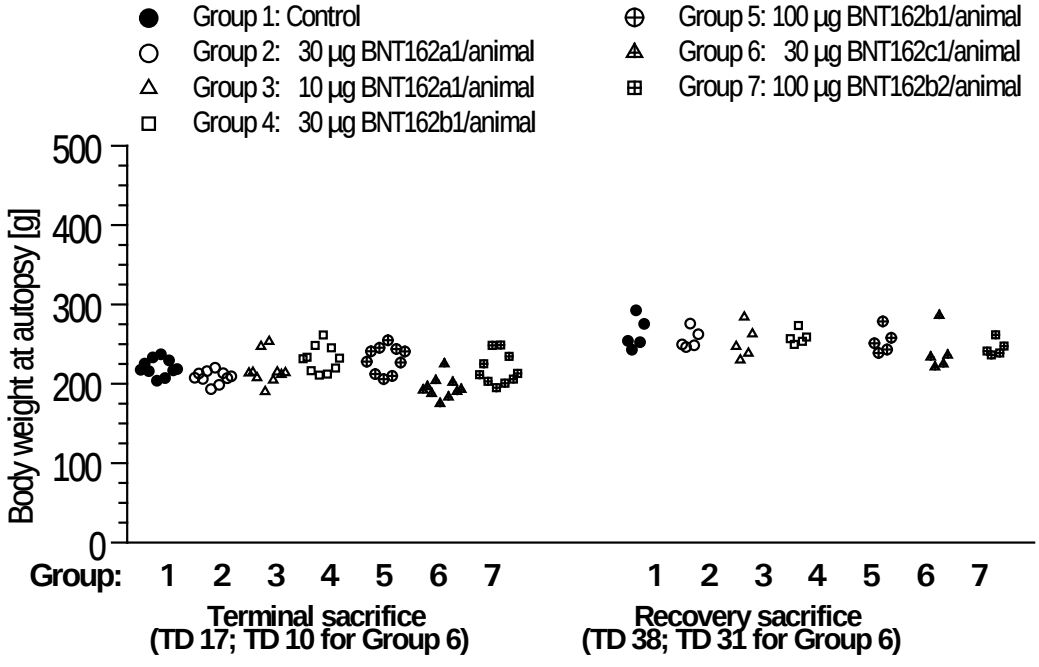


Figure 1-6 Body weight at autopsy, individual data -Females



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4.5 Food and drinking water consumption

BNT162a1 - Groups 2 and 3

Treatment period

No test item-related influence was observed on the relative food consumption for the male and female animals following intramuscular treatment with **10 µg BNT162a1/animal** (group 3) on test days 1, 8, and 15 (3 administrations) in comparison to the control.

The relative food consumption of the male animals treated with **30 µg BNT162a1/animal** (group 2) appeared to be slightly decreased by 5.7% in test week 1 and by 7.2% in test week 2 (statistically significant at $p \leq 0.05$ and $p \leq 0.01$). For the female animals of group 2, a slight decrease of the relative food consumption by 3.3% in test week 1 and by 4.4% in test week 2 was observed (not statistically significant). The effect is considered to be test item related.

Recovery period

No noteworthy changes were noted for the relative food consumption of the male and female animals previously treated with **10** or **30 µg BNT162a1/animal** (groups 3 and 2) in comparison to the control animals during the recovery period.

BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery period

No test item-related influence was observed on the relative food consumption for the male and female animals following intramuscular treatment with **10** or **30 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** (group 6) on test days 1 and 8 (2 administrations) in comparison to the control group throughout the treatment and recovery period.

Any differences to the control group are regarded to be within the normal range of biological variation.

The statistically significant differences to the control group's relative food consumption that are not considered to be related to any of the test items are listed in the text table on the following page.

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Text table 4-4: Statistically significant changes in relative food consumption considered not test item-related

Statistically significant changes in relative food consumption (refer to Table 4-1) in comparison to the control group considered not test-item-related							
Group	**Test item no.#**	**Dose [µg/animal]**	**Sex**	**Test week**	**Change [%]**	**Statistical significance**	**Reason**
2	1	30	m	4	+15.6	$p \leq 0.01$	B
				5	+10.7	$p \leq 0.01$	B
3	1	10	m	1	-16.9	$p \leq 0.01$	C
				2	-10.3	$p \leq 0.01$	C
				3	-11.1	$p \leq 0.01$	C
			f	1	-6.5	$p \leq 0.05$	C
5	3	100	m	1	-22.9	$p \leq 0.01$	C
				2	-12.2	$p \leq 0.01$	C
				3	-12.3	$p \leq 0.01$	C
			f	1	-13.3	$p \leq 0.01$	C
				4	+12.6	$p \leq 0.05$	A
6	5	30	m	1	-18.5	$p \leq 0.01$	C
				2	-13.7	$p \leq 0.01$	C
			f	1	-9.7	$p \leq 0.01$	C
7	4	100	m	1	-22.3	$p \leq 0.01$	C
				2	-11.1	$p \leq 0.01$	C
				3	-13.4	$p \leq 0.01$	C
			f	1	-13.7	$p \leq 0.01$	C
				4	+13.2	$p \leq 0.01$	B

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change is within limits of normal biological variation and without toxicological relevance.
B Change is due to the lower weight of the respective animals.
C Change is due to the higher weight of the respective animals.

Visual appraisal of the drinking water consumption did not reveal any noteworthy differences between any of the test item-treated groups and the control group throughout the treatment and recovery period. The consumption was not quantified.

Mean values per group and individual data of food intake are listed in Table 4-1 (Food Consumption - Summary) and Table 4-2 (Food Consumption - Individual Data).

The mean relative food consumption (in g/kg b.w./day) per group and sex is shown graphically in Figure 2-1 (males) and Figure 2-2 (females) on the following page.

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Figure 2-1 Food consumption of male rats treated once weekly, mean values per group
Up to 3 administrations per animal (TD 1/8/15)

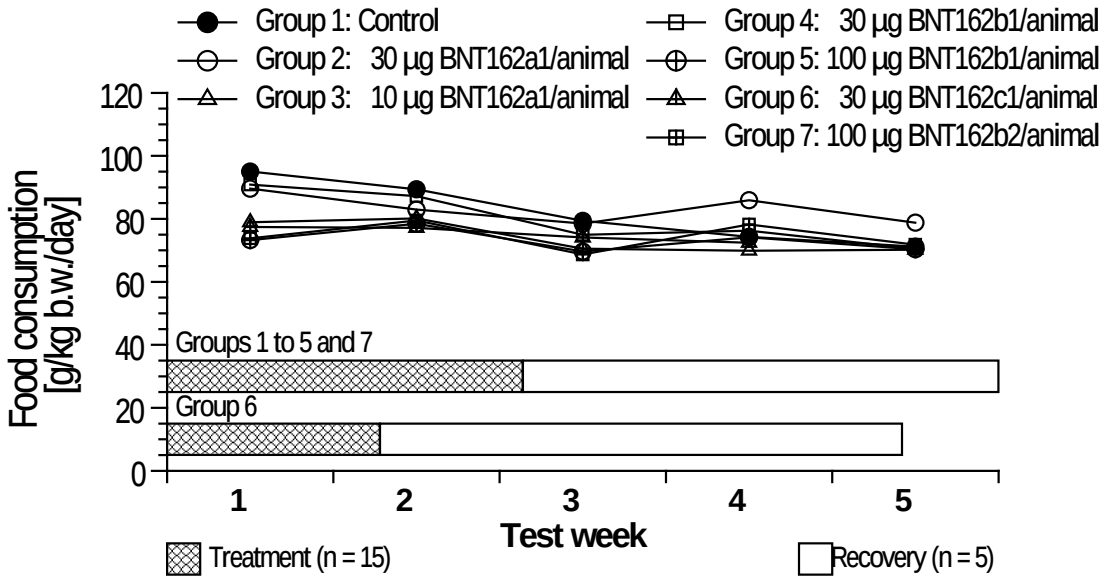
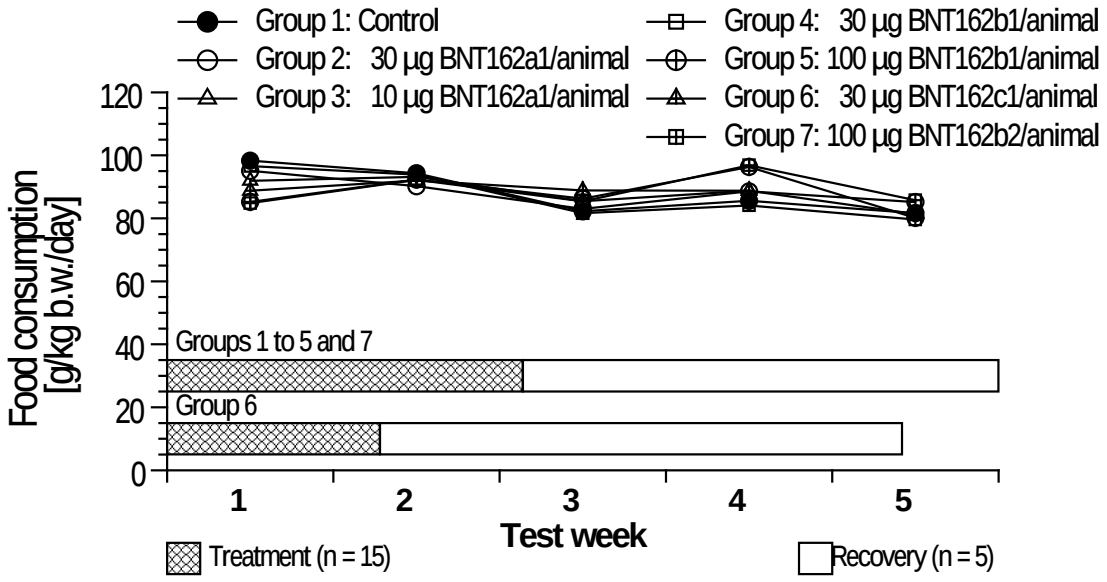


Figure 2-2 Food consumption of female rats treated once weekly, mean values per group
Up to 3 administrations per animal (TD 1/8/15)



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4.6 Body temperature

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment and recovery period

Intramuscular treatment with **10** or **30 µg BNT162a1/animal** (groups 3 and 2), **30** or **100 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15 (3 administrations), or with **30 µg BNT162c1/animal** (group 6) on test days 1 and 8 (2 administrations) led to slightly increased body temperatures at 4 h p.a. and/or 24 h p.a. compared to the control animals (statistically significant at $p \leq 0.01$ or $p \leq 0.05$ in many cases). The effect appeared to be slightly more pronounced in the groups treated with the higher test item dose levels (i.e. groups 2, 5, 6, and 7).

During the recovery period, the body temperature remained at a slightly higher level compared to the control group in all previously test item treated groups.

The slight body temperature *decreases* noted for groups 3, 5, 6, and 7 in comparison to the control group are considered to be due to the circumstances of the time-shift in study conduct for these groups. The body temperature measurements of these animals were performed on dates different from those for the control and by different staff.

Mean values per group and individual data of body temperature are listed in Table 5-1 (Body Temperature - Summary) and Table 5-2 (Body Temperature - Individual Data).

The mean body temperature per group and sex is shown graphically in Figure 3-1 (males) and Figure 3-2 (females) on the following page.

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Figure 3-1 Body temperature of male rats treated once weekly, mean values per group

Up to 3 administrations per animal (TD 1/8/15)

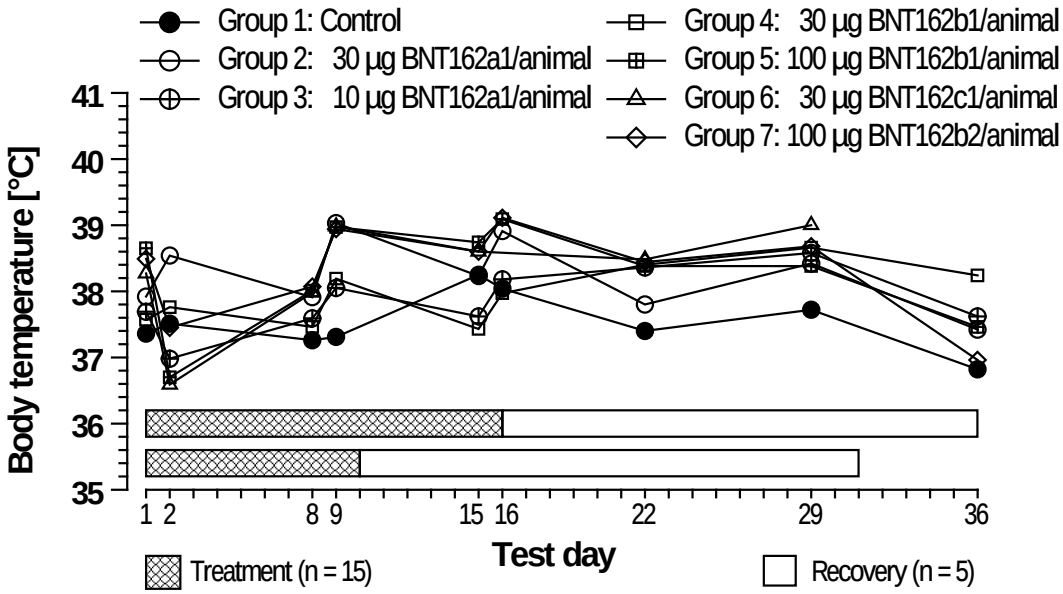
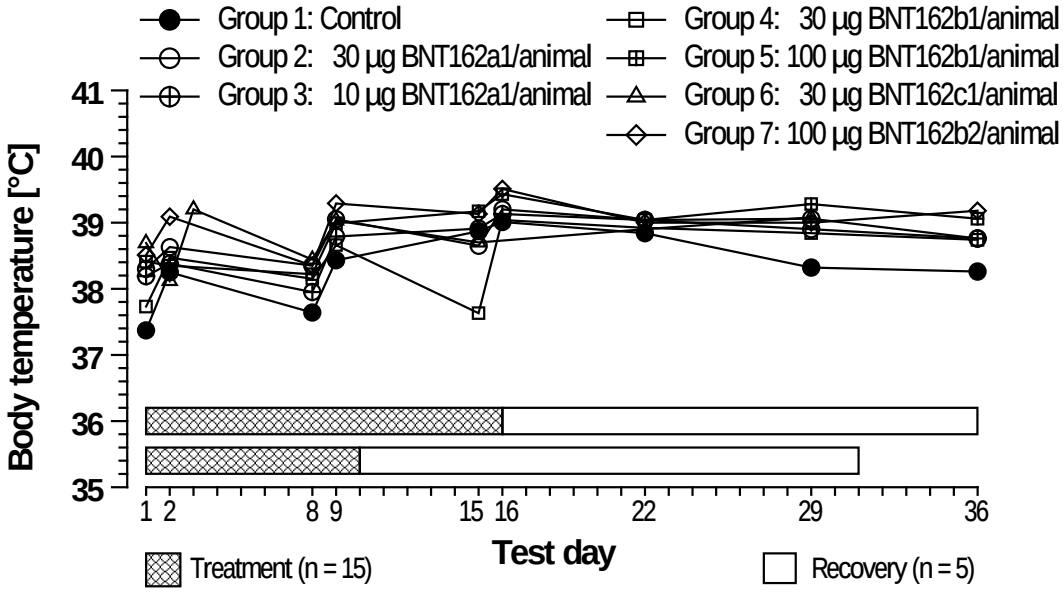


Figure 3-2 Body temperature of female rats treated once weekly, mean values per group

Up to 3 administrations per animal (TD 1/8/15)



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4.7 Haematology and coagulation

The most consistent test item-related haematologic changes were dose-related increases in neutrophils and large unstained cells (LUC), which were seen with all test items on test day 17, but were greatest in groups 2, 5 and 7 and were greater in females relative to males. Other test item-related changes included decreases in the absolute and relative reticulocyte count (test day 4 only), platelet count, and red cell mass (HGB, HCT and RBC; test day 17 only), and increases in the numbers of leucocytes, monocytes, eosinophils, basophils and/or fibrinogen concentrations. All changes were considered to be related to the primary pharmacodynamic activity of the vaccines, which induce a potent immune response.

Increases in fibrinogen levels and leucocytes (most notably neutrophils and LUC), were consistent with an acute phase response secondary to immune activation and inflammation at the injection sites.

Decreases in numbers of reticulocytes, RBC and platelets were associated with increased bone marrow haematopoiesis, consistent with transient, secondary or peripheral effects. Transient reticulocyte decreases (test day 4 only) were likely secondary to the acute phase response and inflammation. Effects on red cell mass were limited to minimal decreases in RBC, HGB, and HCT on test day 17. Platelet decreases were small in magnitude and not expected to result in bleeding. They were likely secondary to inflammation-related platelet activation and consumption. There were no thrombi evident microscopically.

BNT162a1 - Groups 2 and 3

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **10 µg BNT162a1/animal** (group 3) or **30 µg BNT162a1/animal** (group 2) are given in the text table on the following page.

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Text table 4-5: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162a1

Test item-related changes in haematological and coagulation parameters, groups 2 and 3 compared to the control group in % (refer to Table 6-1)				
Parameter	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
Test day 4				
Platelets (PLT)	None	None	None	-22.7**
Reticulocytes (relative)	-64.1**	-52.0**	-75.3**	-62.1**
Reticulocytes (absolute)	-62.1**	-51.5**	-75.6**	-64.4**
Neutrophils (Neut), abs.	None	None	+128.8**	+245.1**
Monocytes (Mono), abs.	None	None	+39.0	+129.5**
Large unclassified cells (LUC), abs.	None	None	+644.9**	+574.7**
Basophils (Baso), abs.	None	None	None	+119.2**
Test day 17				
Haemoglobin (HGB)	None	-7.7**	None	None
Erythrocytes (RBC)	None	-5.4*	None	None
Haematocrit (HCT)	None	-9.7**	None	None
Leucocytes (WBC)	None	None	+79.1**	+104.1**
Platelets (PLT)	-26.1**	-34.6**	-26.1**	-41.7**
Neutrophils (Neut), abs.	+267.1**	+338.0**	+430.6**	+589.4**
Monocytes (Mono), abs.	+103.6**	+131.7**	+84.7*	+97.4*
Large unclassified cells, (LUC) abs.	+455.7**	+520.8**	+1226.1**	+1022.1**
Basophils (Baso), abs.	+130.0**	+105.3*	+110.0**	+215.8**
Fibrinogen	+155.4**	+144.5*	+191.3**	+174.4**

abs. absolute

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **10 µg BNT162a1/animal** (group 3) or **30 µg BNT162a1/animal** (group 2) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

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BNT162b1 - Groups 4 and 5

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, eosinophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **30** or **100 µg BNT162b1/animal** (groups 4 and 5) are given in the text table below.

Text table 4-6: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162b1

Test item-related changes in haematological and coagulation parameters, groups 4 and 5 compared to the control group in % (refer to Table 6-1)				
Parameter	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Test day 4				
Reticulocytes (relative)	-43.0	None	-65.6**	-42.6**
Reticulocytes (absolute)	-44.3**	None	-63.3**	-42.6**
Large unclassified cells (LUC), abs.	None	None	None	+250.6**
Test day 17				
Haemoglobin (HGB)	None	-10.5**	-10.9**	-13.5**
Erythrocytes (RBC)	None	-8.2**	-5.6	-9.5**
Haematocrit (HCT)	None	-9.1**	-13.9**	-14.7**
Leucocytes (WBC)	None	+79.3**	+82.2**	+102.7**
Platelets (PLT)	None	None	-25.0**	-34.4**
Neutrophils (Neut), abs.	+304.2**	+486.1**	+447.3**	+636.3**
Monocytes (Mono), abs.	+102.3**	+134.4**	+77.9*	+113.8**
Eosinophils (Eos), abs.	+111.9**	+227.7**	+230.3**	+440.4**
Large unclassified cells (LUC), abs.	+169.3**	+457.1**	+575.0**	+714.3**
Basophils (Baso), abs.	+100.0**	+121.1**	+110.0**	+126.3**
Fibrinogen	+155.7**	+146.2**	+192.1**	+161.4**

abs. absolute

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

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Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **30** or **100 µg BNT162b1/animal** (groups 4 and 5) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

BNT162c1 - Group 6

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **30 µg BNT162c1/animal** (group 6) are given in the text table below.

Text table 4-7: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162c1

Test item-related changes in haematological and coagulation parameters, group 6 compared to the control group in % (refer to Table 6-1)		
Parameter	**Group 6: 30 µg BNT162c1/animal**	
	Males	**Females**
Test day 4		
Reticulocytes (relative)	-76.5**	-59.0**
Reticulocytes (absolute)	-74.9**	-59.3**
Neutrophils (Neut), abs.	+68.4**	+104.9**
Monocytes (Mono), abs.	+38.7	+93.7**
Large unclassified cells (LUC), abs.	+360.7**	+283.9**
Basophils (Baso), abs.	+130.8**	None

- Text table continued on the next page -

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Test item-related changes in haematological and coagulation parameters, group 6 compared to the control group in % (refer to Table 6-1)		
Parameter	**Group 6: 30 µg BNT162c1/animal**	
	Males	**Females**
- Text table continued from previous page -		
Test day 10		
Haemoglobin (HGB)	None	↓
Erythrocytes (RBC)	None	↓
Haematocrit (HCT)	None	↓
Leucocytes (WBC)	↑	↑
Platelets (PLT)	↓	↓
Neutrophils (Neut), abs.	↑	↑
Monocytes (Mono), abs.	↑	↑
Large unclassified cells (LUC), abs.	↑	↑

abs. absolute
↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.
↓ Decrease relative to study control range, but % difference not quantifiable due to lacking concurrent controls.
None No test item-related change.
*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **30 µg BNT162c1/animal** (group 6) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

BNT162b2 - Group 7

Treatment period

Test item-related changes included decreases in the absolute and relative reticulocyte count, the number of platelets, and red cell mass, and increases in the numbers of leucocytes, neutrophils, eosinophils, monocytes, large unstained cells (LUC), basophils and/or the levels of fibrinogen. All changes fully reversed by the end of the recovery phase.

The test item-related changes noted for the animals treated with **100 µg BNT162b2/animal** (group 7) as given in the text table on the following page.

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Text table 4-8: Test item-related changes in haematological and coagulation parameters for the treatment with BNT162b2

Test item-related changes in haematological and coagulation parameters, group 7 compared to the control group in % (refer to Table 6-1)		
Parameter	**Group 7: 100 µg BNT162b2/animal**	
	Males	**Females**
Test day 4		
Reticulocytes (relative)	-74.3**	-47.7**
Reticulocytes (absolute)	-72.1**	-48.2**
Large unclassified cells (LUC), abs.	+295.5**	+319.5**
Basophils (Baso), abs.	+150.0**	None
Test day 17		
Haemoglobin (HGB)	-9.1**	-12.7**
Erythrocytes (RBC)	None	-9.8**
Haematocrit (HCT)	-11.9**	-13.5**
Leucocytes (WBC)	+118.7**	+111.0**
Platelets (PLT)	-29.2**	-34.1**
Neutrophils (Neut), abs.	+605.8**	+679.8**
Eosinophils (Eos), abs.	+419.3**	+509.6**
Large unclassified cells, (LUC) abs.	+685.2**	+594.8**
Basophils (Baso), abs.	+146.7**	+105.3*
Fibrinogen	+205.2**	+160.2**

abs. absolute

None No test item-related change.

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

Recovery period

No noteworthy differences were noted for any haematological or coagulation parameter between the animals previously treated with **100 µg BNT162b2/animal** (group 7) and the control animals at the end of the treatment period. All test item-related changes previously noted during the treatment period had subsided.

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No test item-related effects were observed for the the numbers of lymphocytes, the prothrombin time (PT), the activated partial thromboplastin time (aPTT), the mean corpuscular volume (MCV), the mean corpuscular haemoglobin (MCH), the mean corpuscular haemoglobin concentration (MCHC), the mean platelet (thrombocyte) volume (MPV), the relative volume of thrombocytes / Plateletcrit (PCT), the platelet distribution width (PDW), the red cell distribution width (RDW), and the mean platelet component (MPC) for any of the test items during the treatment period and at the end of the recovery period. All data of the parameters given before are considered to be within the normal range of biological variability.

Statistically significant differences in haematological and coagulation parameters noted in comparison to the control group during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental are listed in the text table starting below.

Text table 4-9: Statistically significant differences in haematological and coagulation parameters considered not test item-related

Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Haemoglobin content (HGB)	2	1	30	m	17	-5.1	$p \leq 0.01$	A
	3	1	10	m	4	+4.5	$p \leq 0.05$	A
					17	-4.9	$p \leq 0.01$	A
	4	3	30	m	4	-4.5	$p \leq 0.05$	A
					17	-5.7	$p \leq 0.01$	A
	5	3	100	m	4	+3.8	$p \leq 0.05$	A
	6	5	30	m	4	+4.1	$p \leq 0.05$	A
	7	4	100	m	4	+5.9	$p \leq 0.01$	A
Erythrocytes (RBC)	3	1	10	m	4	+6.7	$p \leq 0.01$	A
	5	3	100	m	4	+7.1	$p \leq 0.01$	A
	6	5	30	m	4	+7.2	$p \leq 0.01$	A
	7	4	100	m	4	+8.0	$p \leq 0.01$	A
Leucocytes (WBC)	2	1	30	f	4	+53.2	$p \leq 0.01$	A
	3	1	10	m	17	+62.4	$p \leq 0.01$	A
				f	17	+55.0	$p \leq 0.05$	A
	4	3	30	m	17	+60.7	$p \leq 0.01$	A
	6	5	30	m	4	+37.6	$p \leq 0.01$	A
	7	4	100	m	4	+37.0	$p \leq 0.01$	A

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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Reticulocytes (rel.)	2	1	30	m	17	-23.6	$p \leq 0.01$	A
	4	3	30	f	4	-25.0	$p \leq 0.01$	A
	7	4	100	m	17	-23.3	$p \leq 0.01$	A
Reticulocytes (abs.)	2	1	30	m	17	-25.5	$p \leq 0.01$	A
	3	1	10	m	17	-18.8	$p \leq 0.05$	A
	4	3	30	m	17	-19.6	$p \leq 0.05$	A
				f	4	-26.5	$p \leq 0.05$	A
	7	4	100	m		-26.3	$p \leq 0.01$	A
Platelets (PLT)	4	3	30	f	17	-17.9	$p \leq 0.01$	A
Haematocrit value (HCT)	2	1	30	m	17	-5.8	$p \leq 0.01$	A
	3	1	10	m	17	-8.7	$p \leq 0.01$	A
	4	3	30	m	4	-3.6	$p \leq 0.05$	A
					17	-5.3	$p \leq 0.01$	A
Neutrophils (Neut), abs.	7	4	100	f	4	+126.9	$p \leq 0.01$	A
Lymphocytes (Lym), abs.	6	5	30	m	4	+28.0	$p \leq 0.05$	A
	7	4	100	m	4	+36.8	$p \leq 0.01$	A
Eosinophils (Eos), abs.	3	1	10	f	17	+61.7	$p \leq 0.05$	A
Large unclassified cells (LUC), abs.	3	1	10	m	4	+146.1	$p \leq 0.01$	A
				f	4	+113.8	$p \leq 0.01$	A
	5	3	100	m	4	+151.7	$p \leq 0.01$	A
Basophils (Baso), abs.	3	1	10	m	4	+80.8	$p \leq 0.05$	A
	7	4	100	f	4	+65.4	$p \leq 0.05$	A
Activated partial thromboplastin time (aPTT)	2	1	30	m	17	+15.5	$p \leq 0.01$	A
				f	17	+16.6	$p \leq 0.01$	A
	3	1	10	m	17	+18.2	$p \leq 0.01$	A
				f	17	+23.3	$p \leq 0.01$	A
	5	3	100	f	17	+13.7	$p \leq 0.01$	A
	7	4	100	m	17	+14.1	$p \leq 0.05$	A
				f	17	+18.1	$p \leq 0.01$	A
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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Mean corpuscular volume (MCV)	2	1	30	m	17	-2.9	$p \leq 0.05$	A
	3	1	10	m	4	-4.4	$p \leq 0.01$	A
					17	-7.3	$p \leq 0.01$	A
				f	17	-4.5	$p \leq 0.01$	A
	4	3	30	m	17	-2.7	$p \leq 0.05$	A
	5	3	100	m	4	-5.4	$p \leq 0.01$	A
					17	-8.7	$p \leq 0.01$	A
				f	17	-5.8	$p \leq 0.01$	A
	6	5	30	m	4	-5.2	$p \leq 0.01$	A
	7	4	100	m	4	-5.3	$p \leq 0.01$	A
					17	-8.6	$p \leq 0.01$	A
				f	17	-4.0	$p \leq 0.05$	A
Mean corpuscular haemoglobin (MCH)	3	1	10	m	17	-3.6	$p \leq 0.01$	A
	4	3	30	m	17	-3.3	$p \leq 0.01$	A
	5	3	100	m	17	-5.7	$p \leq 0.01$	A
				f	17	-4.3	$p \leq 0.01$	A
	7	4	100	m	17	-6.0	$p \leq 0.01$	A
Mean corpuscular haemoglobin concentration (MCHC)	2	1	30	m	4	+1.4	$p \leq 0.05$	A
	3	1	10	m	4	+2.7	$p \leq 0.01$	A
					17	+4.1	$p \leq 0.01$	A
				f	4	+2.0	$p \leq 0.01$	A
					17	+2.1	$p \leq 0.01$	A
	4	3	30	f	17	-1.6	$p \leq 0.05$	A
	5	3	100	m	4	+2.7	$p \leq 0.01$	A
					17	+3.3	$p \leq 0.01$	A
				f	17	+1.6	$p \leq 0.05$	A
	6	5	30	m	4	+2.4	$p \leq 0.01$	A
				f	4	+2.6	$p \leq 0.01$	A
	7	4	100	m	4	+3.7	$p \leq 0.01$	A
					17	+3.2	$p \leq 0.01$	A
				f	4	+3.0	$p \leq 0.01$	A

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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Mean platelet (thrombocyte) volume (MPV)	3	1	10	m	17	-20.4	p ≤ 0.01	A
				f	4	-11.1	p ≤ 0.01	A
					17	-17.2	p ≤ 0.01	A
	5	3	100	m	17	-17.1	p ≤ 0.01	A
				f	4	-8.1	p ≤ 0.05	A
					17	-13.4	p ≤ 0.01	A
	6	5	30	f	4	-7.6	p ≤ 0.05	A
	7	4	100	m	17	-14.2	p ≤ 0.01	A
				f	17	-11.6	p ≤ 0.01	A
Relative volume of thrombocytes / Plateletcrit (PCT)	2	1	30	m	17	-20.3	p ≤ 0.01	A, B
				f	4	-18.2	p ≤ 0.05	A
					17	-36.6	p ≤ 0.01	A, B
	3	1	10	m	17	-41.5	p ≤ 0.01	A, B
				f	17	-46.5	p ≤ 0.01	A, B
	4	3	30	f	17	-20.1	p ≤ 0.01	A, B
	5	3	100	m	17	-37.9	p ≤ 0.01	A, B
				f	17	-43.4	p ≤ 0.01	A, B
	7	4	100	m	17	-38.7	p ≤ 0.01	A, B
				f	17	-43.2	p ≤ 0.01	A, B
Platelet distribution width (PDW)	2	1	30	m	4	+25.1	p ≤ 0.01	A
					17	+25.3	p ≤ 0.01	A, B
				f	17	+21.0	p ≤ 0.01	A, B
	3	1	10	m	4	+17.4	p ≤ 0.01	A
					17	+50.0	p ≤ 0.01	A, B
				f	17	+46.1	p ≤ 0.01	A, B
	4	3	30	m	17	+8.5	p ≤ 0.05	A, B
	5	3	100	m	4	+14.0	p ≤ 0.05	A
					17	+47.1	p ≤ 0.01	A, B
				f	17	+48.8	p ≤ 0.01	A, B
	6	5	30	m	4	+23.3	p ≤ 0.01	A
	7	4	100	m	4	+24.7	p ≤ 0.01	A
					17	+45.8	p ≤ 0.01	A, B
				f	17	+42.4	p ≤ 0.01	A, B
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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Red cell distribution width (RDW)	2	1	30	m	4	+6.2	$p \leq 0.01$	A
					17	+7.3	$p \leq 0.01$	A
					38	+17.7	$p \leq 0.01$	A, B
				f	17	+11.1	$p \leq 0.01$	A
					38	+14.9	$p \leq 0.01$	A, B
	3	1	10	m	17	-12.2	$p \leq 0.01$	A
					38	+18.8	$p \leq 0.01$	A, B
				f	17	-8.7	$p \leq 0.01$	A
					38	+12.9	$p \leq 0.01$	A, B
	4	3	30	m	17	+8.9	$p \leq 0.01$	A
					38	+16.9	$p \leq 0.01$	A, B
				f	17	+6.1	$p \leq 0.05$	A
					38	+12.4	$p \leq 0.05$	A, B
	5	3	100	m	17	-12.2	$p \leq 0.01$	A
					38	+16.0	$p \leq 0.01$	A, B
				f	17	-6.7	$p \leq 0.05$	A
					38	+14.8	$p \leq 0.01$	A, B
	7	4	100	m	17	-12.0	$p \leq 0.01$	A
					38	+15.3	$p \leq 0.01$	A, B
				f	17	-6.2	$p \leq 0.05$	A
					38	+14.8	$p \leq 0.01$	A, B
Mean platelet component (MPC)	2	1	30	m	4	+10.1	$p \leq 0.01$	A
					17	+9.1	$p \leq 0.01$	A, B
				f	17	+11.0	$p \leq 0.01$	A, B
	3	1	10	m	4	+13.5	$p \leq 0.01$	A
					17	+17.2	$p \leq 0.01$	A, B
				f	4	+12.5	$p \leq 0.01$	A
					17	+14.5	$p \leq 0.01$	A, B
					38	+9.5	$p \leq 0.05$	A
	4	3	30	f	17	+8.8	$p \leq 0.01$	A, B
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Statistically significant differences in haematological and coagulation parameters in comparison to the control group considered not test item-related (refer to Table 6-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Mean platelet component (MPC) *- continued*	5	3	100	m	4	+13.0	$p \leq 0.01$	A
					17	+19.5	$p \leq 0.01$	A, B
				f	4	+14.3	$p \leq 0.01$	A
					17	+20.2	$p \leq 0.01$	A, B
					38	+12.7	$p \leq 0.01$	A
	6	5	30	m	4	+14.0	$p \leq 0.01$	A, B
				f	4	+11.8	$p \leq 0.01$	A
	7	4	100	m	4	+15.8	$p \leq 0.01$	A
					17	+18.7	$p \leq 0.01$	A, B
				f	4	+14.8	$p \leq 0.01$	A
					17	+18.3	$p \leq 0.01$	A, B
					38	+14.4	$p \leq 0.01$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

abs. absolute count
rel. relative count

A Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
B Change is due to the relative high or low value noted for the control group.

Group mean values of haematological and coagulation parameters are presented in Table 6-1 (Haematological Parameters - Summary), individual data are listed in Table 6-2 (Haematological Parameters - Individual Data).

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4.8 Clinical chemistry

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period

An elevated plasma activity of gamma-glutamyltransferase (gamma-GT) was noted for all test item-treated groups in comparison to the control group as given in the text table below. There were no macroscopic or microscopic findings (see Section 4.14 and Section 4.16) consistent with cholestasis or hepatobiliary injury to explain the increased gamma-GT.

Text table 4-10: Test item-related changes in plasma activity of gamma-glutamyltransferase

Test item-related changes in plasma activity of gamma-glutamyltransferase (gamma-GT) compared to the control group in % (refer to Table 7-1)								
Test day	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
4	+208.4**	+212.5**	+343.2**	+317.0**	+165.3**	+163.6	+249.5**	+322.7**
17	+87.7**	+174.4**	+173.5**	+228.1**	+121.6**	+225.6**	+158.0**	+263.6**
Test day	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
4	+278.9**		+328.4**		+242.1**		+355.7**	
10	↑		↑					
17					+198.1**		+317.4**	

*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

The range of individual data noted for the gamma-GT activity in several test groups slightly exceeded the range of (b) (4) historical data as summarised in the text table on the following page.

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Text table 4-11: Comparison of gamma-glutamyltransferase activity observed in this study to (b) (4) historical data

Enzyme activity of gamma-glutamyltransferase (gamma-GT) [U/mL plasma]					
Sex	Group	Data observed in this study[#1] Mean (Range of individual data)			(b) (4) historical Data[#2] Mean (Range of individual data)
		TD 4	TD 10[#3]/17	TD 31[#3]/38	
Males	1	0.95 (0.1 - 2.4)	1.62 (0.7 - 2.9)	2.60 (1.6 - 3.6)	2.28 (0.4 - 5.1)
	2	4.21 (2.6 - 5.6)	4.43 (3.2 - 5.6)	2.74 (2.5 - 3.5)	
	3	2.93 (1.8 - 3.6)	3.04 (1.5 - 4.5)	1.88 (1.1 - 2.6)	
	4	2.52 (1.4 - 3.1)	3.59 (2.9 - 4.5)	2.30 (1.6 - 3.0)	
	5	3.52 (2.4 - 4.4)	4.18 (2.8 - 6.0)	1.34 (0.3 - 2.3)	
	6	3.60 (1.4 - 5.2)	3.98 (2.8 - 6.1)	1.84 (1.2 - 2.3)	
	7	3.25 (1.3 - 4.9)	4.83 (3.6 - 6.5)	1.82 (0.5 - 3.2)	
Females	1	0.88 (0.1 - 1.9)	1.21 (0.6 - 2.4)	2.48 (1.2 - 3.0)	2.43 (0.2 - 4.8)
	2	3.67 (1.6 - 5.4)	3.97 (2.9 - 4.7)	3.06 (1.9 - 3.4)	
	3	2.75 (1.6 - 3.4)	3.32 (1.1 - 5.4)	1.74 (0.5 - 2.8)	
	4	2.32 (0.7 - 4.7)	3.94 (2.3 - 6.0)	2.52 (1.4 - 3.2)	
	5	3.72 (1.3 - 5.8)	4.40 (3.7 - 5.2)	2.12 (1.6 - 3.2)	
	6	3.77 (2.4 - 4.7)	4.26 (3.0 - 5.4)	2.14 (1.8 - 2.5)	
	7	4.01 (3.2 - 5.9)	5.05 (4.5 - 6.4)	2.44 (1.8 - 3.5)	

[#1] Age of animals:
Groups 1, 2, and 4: 57 days on test day 4, 70 days on test day 17, 91 days on test day 38.
Groups 3, 5, and 7: 63 days on test day 4, 76 days on test day 17, 97 days on test day 38.
Group 6: 63 days on test day 4, 69 days on test day 10, 90 days on test day 31.

[#2] Obtained from 3 studies conducted at (b) (4) from 2016 to 2018 (in total 45 control group animals per sex, age at examination: 30 to 92 days, treated only with physiological saline or vehicle). The data were not audited by (b) (4) QAU.

[#3] Group 6 only (main study dissection: test day 10, recovery dissection: test day 31).

TD Test day

A graphical presentation of the gamma-glutamyltransferase activity is given in Figure 4-1 (males) and Figure 4-2 (females) on the following page.

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Figure 4-1 Gamma-glutamyltransferase plasma activity in male rats mean values per group and standard deviation

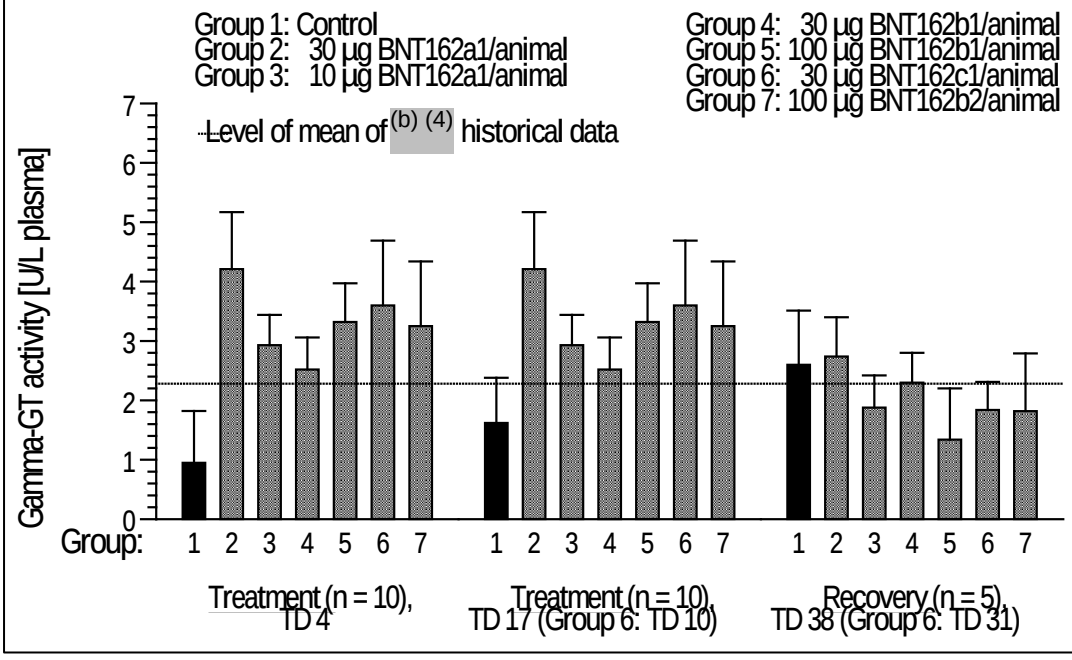
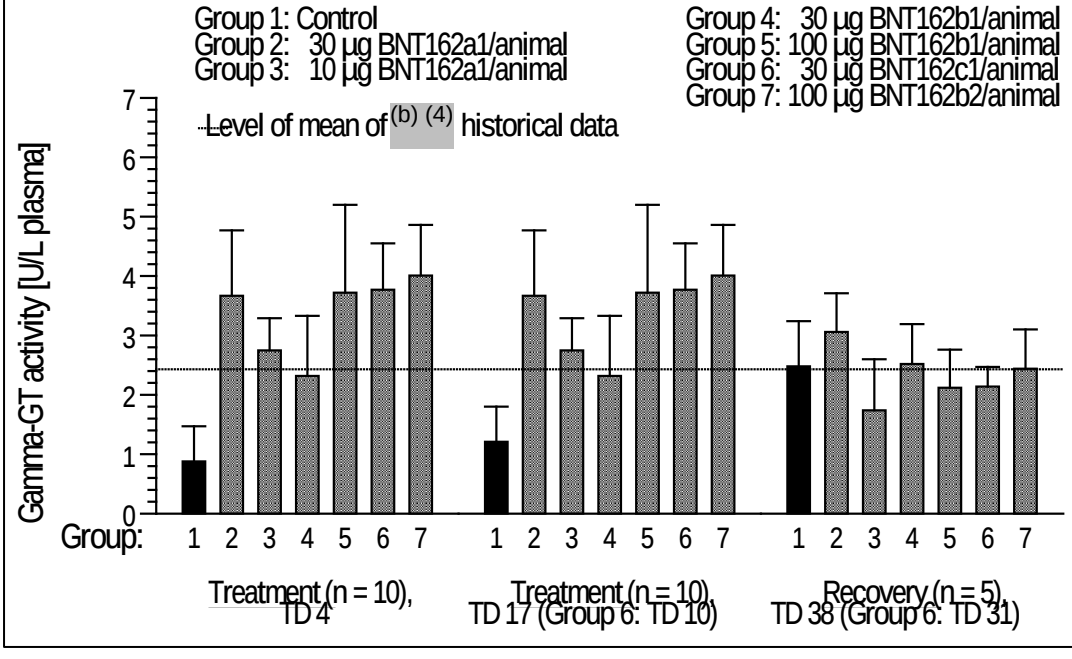


Figure 4-2 Gamma-glutamyltransferase plasma activity in female rats mean values per group and standard deviation



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The elevated plasma activity of gamma-glutamyltransferase is considered to be related to the test item administration, but the cause is unclear.

Further, a decrease in albumin plasma levels and an increase in globulin plasma levels, resulting in an altered albumin/globulin ratio, were observed in all test item treated groups. The changes are consistent with an acute phase response in albumin and globulin where albumin goes down and globulin goes up with inflammation, and the albumin/globulin ratio decreases. The statistically significant changes noted in albumin and globulin levels and the alb./glob. ratio are listed in the text table below.

Text table 4-12: Statistically significant differences in albumin and globulin levels and the albumin/globulin ratio

Statistically significant differences in albumin and globulin levels and the albumin/ globulin ratio compared to the control group (refer to Table 7-1)						
Parameter	**Group**	**Test item**	**Dose [µg/animal]**	**Sex**	**Test day**	**Change [%]**
Albumin	2	BNT162a1	30	m	4	-9.4**
					17	-5.5**
				f	4	-14.1**
					17	-8.8**
	3	BNT162a1	10	m	4	-6.8**
					17	-5.9**
				f	4	-11.3**
					17	-8.8**
	4	BNT162b1	30	m	4	-4.1**
					17	-3.9**
				f	4	-8.4*
					17	-9.8**
	5	BNT162b1	100	m	4	-7.0**
					17	-3.8**
				f	4	-10.8**
					17	-10.5**
	6	BNT162c1	30	m	4	-7.7**
				f	4	-11.7**
	7	BNT162b2	100	m	4	-9.1**
					17	-5.9**
				f	4	-12.6**
					17	-11.0**
Globulin	2	BNT162a1	30	m	4	+9.5**
					17	+9.7**
				f	17	+13.6**

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Statistically significant differences in albumin and globulin levels and the albumin/ globulin ratio compared to the control group (refer to Table 7-1)						
Parameter	**Group**	**Test item**	**Dose [µg/animal]**	**Sex**	**Test day**	**Change [%]**
- Text table continued from previous page -						
Globulin *- continued*	4	BNT162b1	30	m	4	+15.9**
					17	+18.6**
				f	4	+9.5*
					17	+17.9**
	5	BNT162b1	100	m	4	+9.1**
					17	+26.3**
				f	17	+14.4**
	6	BNT162c1	30	m	4	+6.5*
	7	BNT162b2	100	m	4	+7.3*
					17	+23.1**
				f	17	+17.7**
Albumin/Globulin Ratio	2	BNT162a1	30	m	4	-17.1**
					17	-13.9**
				f	4	-18.0**
					17	-19.3**
	3	BNT162a1	10	m	4	-8.4**
					17	-11.7**
	4	BNT162b1	30	m	4	-17.1**
					17	-18.9**
				f	4	-16.3**
					17	-23.6**
	5	BNT162b1	100	m	4	-14.6**
					17	-23.8**
				f	4	-17.0**
					17	-21.7**
	6	BNT162c1	30	m	4	-13.2**
				f	4	-10.1**
	7	BNT162b2	100	m	4	-15.1**
					17	-23.6**
				f	4	-15.7**
					17	-24.4**

m male
f female
*/** Statistically significant at $p \leq 0.01$ / $p \leq 0.05$ (based on numerical data, not on percent difference).

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No other test item-related influence was observed on any of the biochemical parameters for the animals treated with **10** or **30 µg BNT162a1/animal** (groups 3 and 2), **30** or **100 µg BNT162b1/animal** (groups 4 and 5), or **100 µg BNT162b2/animal** (group 7) on test days 1, 8, and 15, or with **30 µg** BNT162c1/**animal** (group 6) on test days 1 and 8 compared to the control animals during the treatment period (test day 4, and test day 10 for group 6/test day 17 for groups 1 to 5 and 7) and at the end of the recovery period.

Recovery period

The elevated plasma activity of gamma-glutamyltransferase noted during the treatment period had subsided in all test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups) and was in a range comparable to that of the control group.

No test item-related effects were noted on the plasma levels of total bilirubin, total cholesterol, creatinine, glucose, phosphate, total protein, urea (in blood), triglycerides, calcium, chloride, potassium, and sodium. No test item related influence was noted on the plasma enzyme activities of alanine aminotransferase (ALAT), alkaline phosphatase (aP), aspartate aminotransferase (ASAT), lactate dehydrogenase (LDH), and creatine kinase (CK). All data of the parameters given above are considered to be within the range of normal biological variability throughout the treatment and recovery period.

Statistically significant differences (at $p \leq 0.01$ or $p \leq 0.05$) were noted for several clinical chemistry parameters between the various test item-treated groups and the control group. The majority of the changes noted were of only marginal degree and occurred in groups 3, 5, 6, and 7, for the animals of which the study conduct started at a later time (see Section 2.7). These animals were 6 days older than the control animals at the time of examination. Blood withdrawal and plasma analysis were performed on dates different from those for the control. An influence of this time offset on the analyses' results cannot be completely excluded.

Statistically significant differences in clinical chemistry parameters in comparison to the control group during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental are listed in the text table on the following page.

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Text table 4-13: Statistically significant differences in clinical chemistry parameters considered not test item-related

Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Globulin	3	1	10	f	38	-19.3	$p \leq 0.01$	A
Albumin/Globulin Ratio	3	1	10	f	38	+18.2	$p \leq 0.01$	A
Bilirubin	2	1	30	m	17	+40.3	$p \leq 0.01$	A
				f	17	+33.3	$p \leq 0.01$	A
	3	1	10	m	4	-26.7	$p \leq 0.01$	A
					17	+31.5	$p \leq 0.01$	A
				f	4	-20.5	$p \leq 0.05$	A
	4	3	30	f	4	-26.8	$p \leq 0.01$	A
	5	3	100	m	4	-27.2	$p \leq 0.01$	A
					17	+46.2	$p \leq 0.01$	A
				f	4	-21.1	$p \leq 0.01$	A
					17	+26.4	$p \leq 0.05$	A
	6	5	30	m	4	-28.8	$p \leq 0.01$	A
	7	4	100	m	4	-25.1	$p \leq 0.01$	A
					17	+42.9	$p \leq 0.01$	A
				f	4	-22.2	$p \leq 0.01$	A
					17	+30.7	$p \leq 0.01$	A
Cholesterol	2	1	30	m	4	-18.7	$p \leq 0.05$	A
					17	-37.5	$p \leq 0.01$	A
	3	1	10	m	17	-21.6	$p \leq 0.05$	A
	4	3	30	m	17	-40.1	$p \leq 0.01$	A
	5	3	100	m	4	-26.4	$p \leq 0.01$	A
					17	-31.5	$p \leq 0.01$	A
	6	5	30	m	4	-19.4	$p \leq 0.05$	A
	7	4	100	m	4	-25.4	$p \leq 0.01$	A
					17	-31.9	$p \leq 0.01$	A
				f	17	-26.0	$p \leq 0.05$	A
Creatinine	3	1	10	m	4	+9.1	$p \leq 0.01$	A
	5	3	100	m	4	+9.8	$p \leq 0.01$	A
					17	+10.0	$p \leq 0.01$	A
	6	5	30	m	4	+7.3	$p \leq 0.01$	A

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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Creatinine *- continued*	7	4	100	m	4	+10.1	$p \leq 0.05$	A
					17	+12.0	$p \leq 0.01$	A
				f	17	+7.3	$p \leq 0.05$	A
Glucose	2	1	30	f	17	-17.7	$p \leq 0.01$	A
	3	1	10	m	4	-30.8	$p \leq 0.01$	A
				f	4	-23.8	$p \leq 0.01$	A
	5	3	100	m	4	-33.6	$p \leq 0.01$	A
				f	17	-14.0	$p \leq 0.01$	A
	6	5	30	m	4	-25.2	$p \leq 0.01$	A
				f	4	-18.5	$p \leq 0.05$	A
	7	4	100	m	4	-26.1	$p \leq 0.01$	A
				f	4	-27.8	$p \leq 0.01$	A
Phosphate	2	1	30	m	17	+18.4	$p \leq 0.01$	A
				f	4	+12.7	$p \leq 0.05$	A
					17	+21.7	$p \leq 0.01$	A
	4	3	30	m	4	-8.8	$p \leq 0.05$	A
	6	5	30	f	4	+14.9	$p \leq 0.01$	A
Protein (total)	2	1	30	f	4	-5.4	$p \leq 0.05$	A
	3	1	10	f	4	-9.4	$p \leq 0.01$	A
					38	-11.8	$p \leq 0.01$	A
	4	3	30	m	4	-5.5	$p \leq 0.01$	A
					17	+6.7	$p \leq 0.01$	A
	5	3	100	m	17	+10.4	$p \leq 0.01$	A
	6	5	30	f	4	-6.9	$p \leq 0.01$	A
	7	4	100	m	17	+7.8	$p \leq 0.01$	A
Triglycerides	2	1	30	m	4	-41.0	$p \leq 0.01$	A
				f	17	+39.7	$p \leq 0.05$	A
	3	1	10	m	4	-70.0	$p \leq 0.01$	A
				f	4	-66.6	$p \leq 0.01$	A
					17	+77.4	$p \leq 0.01$	A
	4	3	30	f	4	-41.9	$p \leq 0.01$	A
	5	3	100	m	4	-73.5	$p \leq 0.01$	A
				f	4	-65.8	$p \leq 0.01$	A

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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)

Parameter	Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -								
Triglycerides *- continued*	6	5	30	m	4	-70.4	$p \leq 0.01$	A
				f	4	-56.5	$p \leq 0.01$	A
	7	4	100	m	4	-73.5	$p \leq 0.01$	A
				f	4	-71.7	$p \leq 0.01$	A
Urea (in blood)	2	1	30	m	17	+20.4	$p \leq 0.01$	A
	3	1	10	m	17	+18.6	$p \leq 0.05$	A
	5	3	100	m	17	+22.5	$p \leq 0.01$	A
	7	4	100	m	17	+35.4	$p \leq 0.01$	A
Calcium	3	1	10	m	4	-6.7	$p \leq 0.01$	A
				f	4	-4.7	$p \leq 0.01$	A
	5	3	100	m	4	-6.6	$p \leq 0.01$	A
	6	5	30	m	4	-9.1	$p \leq 0.01$	A
	7	4	100	m	4	-6.8	$p \leq 0.01$	A
Chloride	2	1	30	f	4	-1.5	$p \leq 0.01$	A
	3	1	10	m	4	+1.2	$p \leq 0.01$	A
	5	3	100	m	4	+2.1	$p \leq 0.01$	A
	6	5	30	m	4	+2.0	$p \leq 0.01$	A
	7	4	100	m	4	+2.1	$p \leq 0.01$	A
Potassium	3	1	10	m	4	-9.3	$p \leq 0.01$	A
				f	4	-9.4	$p \leq 0.05$	A
					17	+11.3	$p \leq 0.05$	A
	5	3	100	m	4	-10.7	$p \leq 0.01$	A
				f	17	+16.4	$p \leq 0.01$	A
	7	4	100	m	4	-8.0	$p \leq 0.05$	A
				f	17	+10.1	$p \leq 0.05$	A
Sodium	2	1	30	f	17	-1.3	$p \leq 0.05$	A
	3	1	10	m	4	+1.0	$p \leq 0.01$	A
					17	-1.2	$p \leq 0.05$	A
	5	3	100	m	4	+1.6	$p \leq 0.01$	A
				f	17	-1.7	$p \leq 0.01$	A
	6	5	30	m	4	+1.2	$p \leq 0.01$	A
	7	4	100	m	4	+1.6	$p \leq 0.01$	A
					17	-1.5	$p \leq 0.01$	A

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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Alanine amino-transferase (ALAT)	2	1	30	f	17	+69.0	$p \leq 0.01$	A
	3	1	10	m	4	-26.2	$p \leq 0.01$	A
				f	4	-20.6	$p \leq 0.05$	A
	5	3	100	m	4	-31.0	$p \leq 0.01$	A
				f	4	-30.0	$p \leq 0.01$	A
	6	5	30	m	4	-33.1	$p \leq 0.01$	A
	7	4	100	m	4	-32.8	$p \leq 0.01$	A
				f	4	-36.5	$p \leq 0.01$	A
Alkaline phosphatase (aP)	2	1	30	m	17	+21.2	$p \leq 0.05$	A
				f	4	+28.4	$p \leq 0.01$	A
					17	+105.4	$p \leq 0.01$	A
	3	1	10	m	4	-32.7	$p \leq 0.01$	A
				f	17	+58.8	$p \leq 0.01$	A
	4	3	30	f	17	+43.2	$p \leq 0.05$	A
	5	3	100	m	4	-27.8	$p \leq 0.01$	A
				f	17	+109.4	$p \leq 0.01$	A
	6	5	30	m	4	-29.8	$p \leq 0.01$	A
	7	4	100	m	4	-22.3	$p \leq 0.01$	A
				f	17	+142.2	$p \leq 0.01$	A
Aspartate amino-transferase (ASAT)	2	1	30	m	17	+26.8	$p \leq 0.01$	A
				f	17	+47.3	$p \leq 0.01$	A
	3	1	10	m	4	+23.9	$p \leq 0.01$	A
				f	4	+32.6	$p \leq 0.01$	A
	5	3	100	f	4	+21.7	$p \leq 0.05$	A
					17	+27.4	$p \leq 0.01$	A
	6	5	30	m	4	+18.8	$p \leq 0.01$	A
				f	4	+43.9	$p \leq 0.01$	A
	7	4	100	m	4	+19.4	$p \leq 0.01$	A
				f	4	+29.7	$p \leq 0.01$	A
					17	+24.3	$p \leq 0.05$	A
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Statistically significant differences in clinical chemistry parameters in comparison to the control group considered not test item-related (refer to Table 7-1)								
Parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
Lactate dehydro-genase (LDH)	5	3	100	m	4	+40.6	$p \leq 0.05$	A
				f	4	+45.2	$p \leq 0.05$	A
	6	5	30	m	4	+49.9	$p \leq 0.01$	A
				f	4	+66.0	$p \leq 0.01$	A
	7	4	100	m	4	+54.1	$p \leq 0.01$	A
				f	4	+54.8	$p \leq 0.05$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
B Change is due to the relative high or low value noted for the control group.

Group mean values of biochemical parameters are presented in Table 7-1 (Biochemical Parameters - Summary), individual data are listed in Table 7-2 (Biochemical Parameters - Individual Data).

4.9 Acute phase proteins

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period

Elevated serum levels of the acute phase proteins alpha1-acid glycoprotein and alpha2 macroglobulin were noted for all test item-treated groups in comparison to the control group on test day 4 and test day 10 or 17 as given in the text tables following on the following page.

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Text table 4-14: Test item-related changes in serum levels of alpha1-acid glycoprotein

Test item-related changes in serum levels of alpha1-acid glycoprotein compared to the control group (refer to Table 8-1), expressed as fold changes (×)								
Test day	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
4	4.7×**	4.1×**	7.2×**	5.0×**	5.9×**	4.7×**	7.0×**	5.6×**
17	14.6×**	12.5×**	8.5×**	9.0×**	8.7×**	8.9×**	19.3×**	18.9×**
Test day	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
4	6.7×**		4.9×**		6.9×**		5.6×**	
10	↑		↑					
17					20.7×**		15.9×**	

** Statistically significant at p ≤ 0.01 (based on the numerical data, not on the fold change).

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

Text table 4-15: Test item-related changes in serum levels of alpha2 macroglobulin

Test item-related changes in serum levels of alpha2 macroglobulin compared to the control group (refer to Table 8-1), expressed as fold changes (×)								
Test day	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
4	5.6×	3.2×**	18.3×**	7.0×**	36.1×**	18.3×**	53.9×**	90.6×**
17	18.6×**	6.4×**	26.0×**	16.8×**	43.8×**	45.1×**	279.2×**	167.7×**
Test day	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
4	17.2×**		9.4×**		54.3×**		75.3×**	
10	↑		↑					
17					216.9×**		120.7×**	

** Statistically significant at p ≤ 0.01 (based on the numerical data, not on the fold change)

↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

All changes noted for the acute phase proteins are considered to be related to the primary pharmacodynamic activity of the intramuscularly delivered vaccines, which induce a local pro-inflammatory environment within the injected muscle and thereby promote a potent immune response.

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Recovery period

The elevated serum levels of alpha1-acid glycoprotein and alpha2 macroglobulin noted during the treatment period had subsided in all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups). The serum levels of both acute phase proteins were in a range comparable to that of the control group in all previously test item-treated groups.

Statistically significant differences in serum levels of acute phase proteins in comparison to the control group noted during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental are listed in the text table below.

Text table 4-16: Statistically significant differences in serum levels of acute phase proteins considered not test item-related

Statistically significant differences in serum levels of acute phase proteins in comparison to the control group considered not test item-related (refer to Table 8-1)								
Acute phase proteins	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Alpha1-acid glycoprotein	3	1	10	m	38	-48.9	$p \leq 0.01$	A
	5	3	100	m	38	-42.7	$p \leq 0.01$	A
				f	38	-53.2	$p \leq 0.05$	A
	7	4	100	m	38	-47.8	$p \leq 0.01$	A
Alpha2 macroglobulin	5	3	100	m	38	+52.9	$p \leq 0.05$	A
	7	4	100	m	38	+63.7	$p \leq 0.05$	A

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7

m male
f female

A Change is due to the relative high or low value noted for the control group.

Mean values per group and individual data of acute phase proteins are listed in Table 8-1 (Acute Phase Protein Levels - Summary) and Table 8-2 (Acute Phase Protein Levels - Individual Data).

The mean acute phase protein levels per group and sex are shown graphically in Figure 5-1 (Alpha1-acid glycoprotein, males), Figure 5-2 (Alpha1-acid glycoprotein, females), Figure 6-1 (Alpha2 macroglobulin, males), and Figure 6-2 (Alpha2 macroglobulin, females) on the following pages.

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Figure 5-1 Alpha1-acid glycoprotein levels in serum of male rats mean values per group and standard deviation

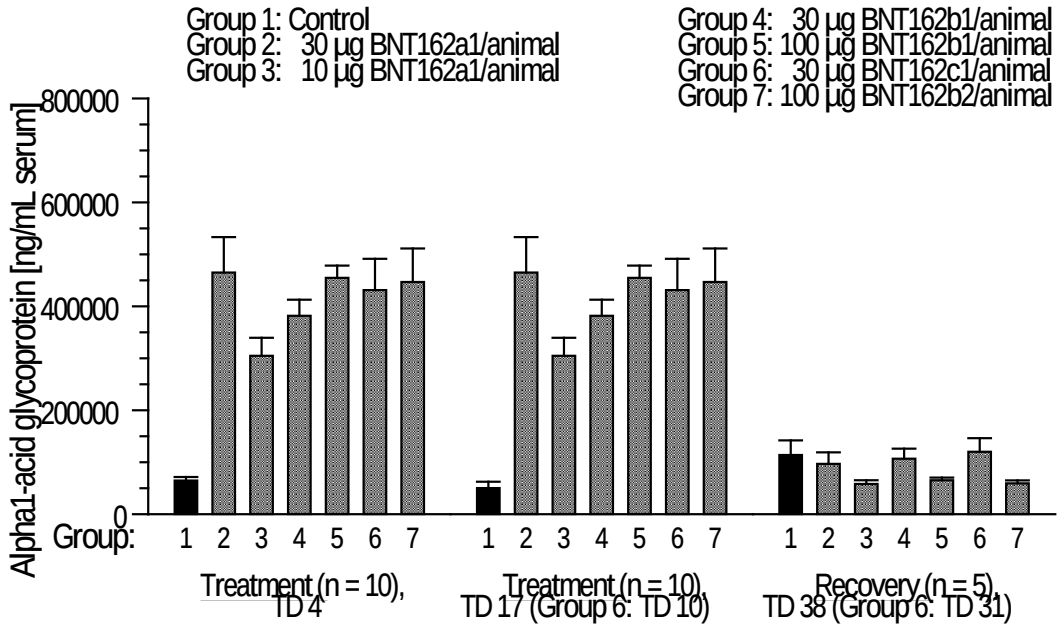
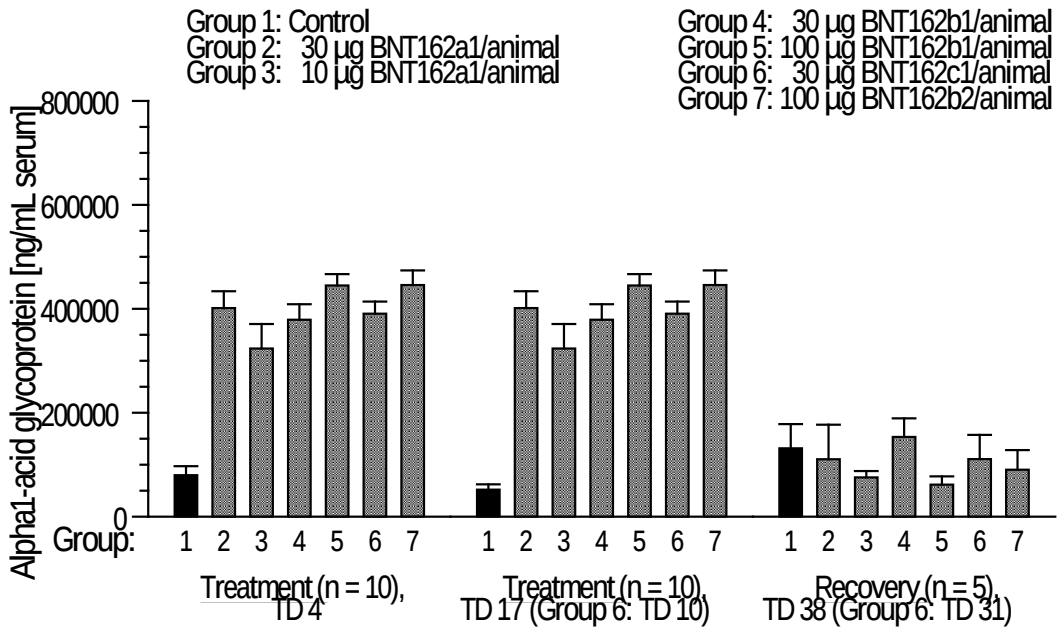


Figure 5-2 Alpha1-acid glycoprotein levels in serum of female rats mean values per group and standard deviation



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Figure 6-1 Alpha2 macroglobulin levels in serum of male rats mean values per group and standard deviation

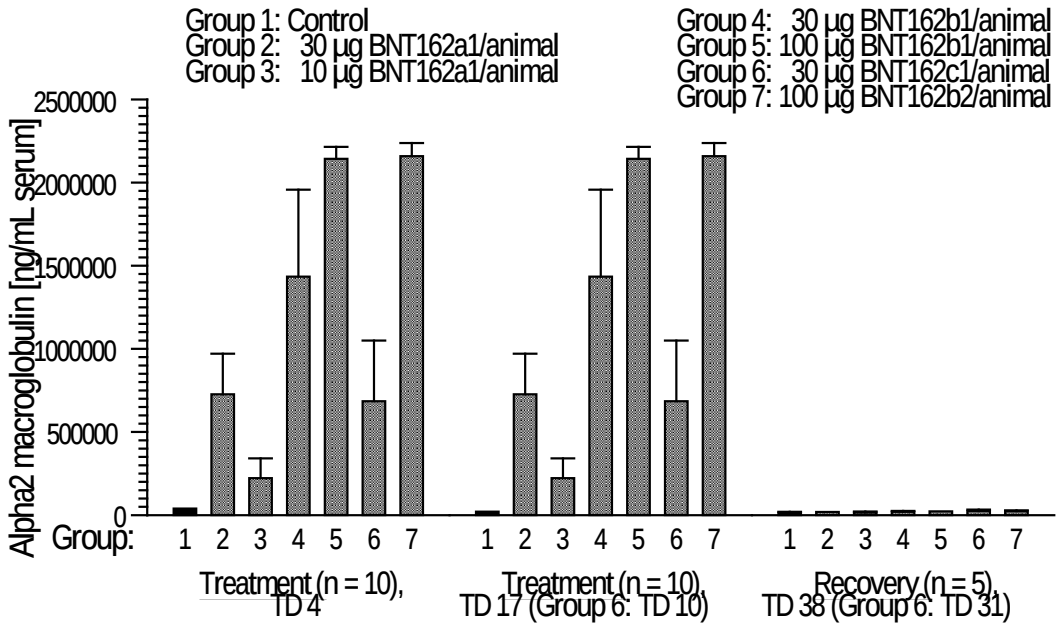
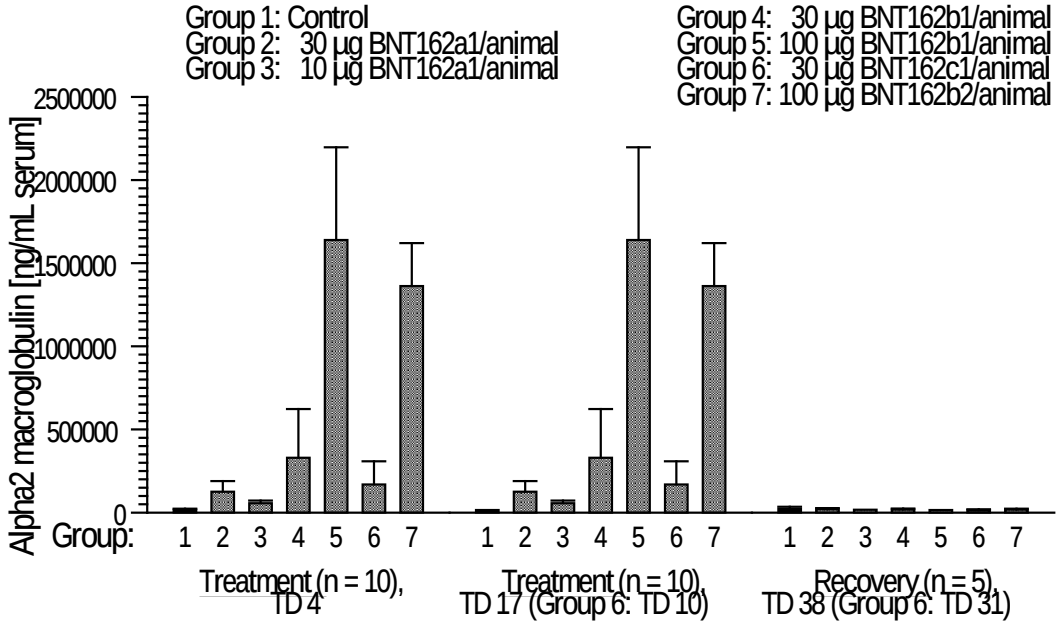


Figure 6-2 Alpha2 macroglobulin levels in serum of female rats mean values per group and standard deviation



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4.10 Cytokines

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery

Elevated serum levels of the cytokines IFN-gamma, TNF-alpha, IL-1beta, IL-6, and IL-10 were noted in all study groups, including the control, compared to the respective predose value as of 6 h p.a. on test day 1. There were no general differences between the test item-treated groups and the control group and among the various test item-treated groups.

A large variability of data was observed using only 3 or 5 animals per group and sex. Therefore, all data obtained are considered to be within the normal range of biological variation. Any differences between the test item-treated animals and the control group are considered as coincidental changes.

Statistically significant differences in cytokine serum levels in comparison to the control group during the treatment period or at the end of the recovery period that are not considered to be test item-related but to be coincidental changes are listed in the text table below.

Text table 4-17: Statistically significant differences in cytokine serum levels considered not test item-related

Statistically significant differences in cytokine serum levels in comparison to the control group considered not test item-related (refer to Table 9-1)								
Cytokine	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day (time point)**	**Change [%]**	**Statistical significance**	**Reason**
IFN-gamma	2	1	30	m	15 (6 h p.a.)	+52.2	$p \leq 0.05$	B
					17 (48 h p.a.)	+2679.2	$p \leq 0.05$	B, C
				f	17 (48 h p.a.)	+342.0	$p \leq 0.05$	B, C
	6	5	30	f	8 (6 h p.a.)	+111.2	$p \leq 0.01$	B
TNF-alpha	3	1	10	m	8 (Predose)	-91.1	$p \leq 0.05$	B

- Text table continued on the next page -

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Statistically significant differences in cytokine serum levels in comparison to the control group considered not test item-related (refer to Table 9-1)								
Cytokine	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day (time point)**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -								
IL-1beta	2	1	30	m	1 (Predose)	+131.7	$p \leq 0.05$	A
	3	1	10	m	8 (Predose)	-96.7	$p \leq 0.05$	B, C
	7	4	100	m	8 (Predose)	-88.6	$p \leq 0.05$	B, C
IL-6	3	1	10	m	1 (6 h p.a.)	-75.7	$p \leq 0.05$	B, D
					15 (6 h p.a.)	+417.0	$p \leq 0.01$	B, C
	5	3	100	m	15 (6 h p.a.)	+468.9	$p \leq 0.01$	B, C
				f	15 (6 h p.a.)	+481.6	$p \leq 0.05$	B, C
	6	5	30	m	1 (6 h p.a.)	-75.7	$p \leq 0.05$	B, D

Test item 1: BNT162a1 - Groups 2 and 3
Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7
Test item 5: BNT162c1 - Group 6

m male
f female

A Change observed predose to start of administration.
B Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
C Change is due to the relative high or low value noted for the control group.
D Change due to mean at level of LLOQ (all individual data are equal to LLOQ).

Mean values per group and individual data of cytokine levels are listed in Table 9-1 (Cytokine Levels - Summary) and Table 9-2 (Cytokine Levels - Individual Data).

The mean cytokine levels per group and sex are shown graphically in Figure 7-1 (IFN-gamma, males), Figure 7-2 (IFN-gamma, females), Figure 8-1 (TNF-alpha, males), Figure 8-2 (TNF-alpha, females), Figure 9-1 (IL-1beta, males), Figure 9-2 (IL-1beta, females), Figure 10-1 (IL-6, males), Figure 10-2 (IL-6, females), Figure 11-1 (IL-10, males), and Figure 11-2 (IL-10, females) on the following pages.

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Figure 7-1 IFN-gamma levels in serum of male rats
mean values per group and standard deviation

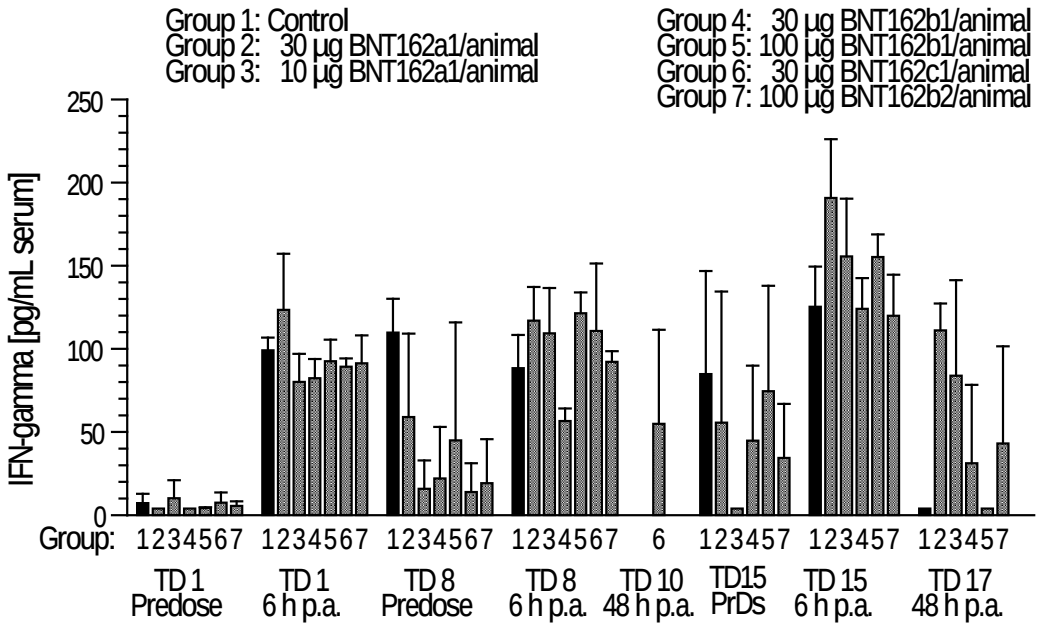
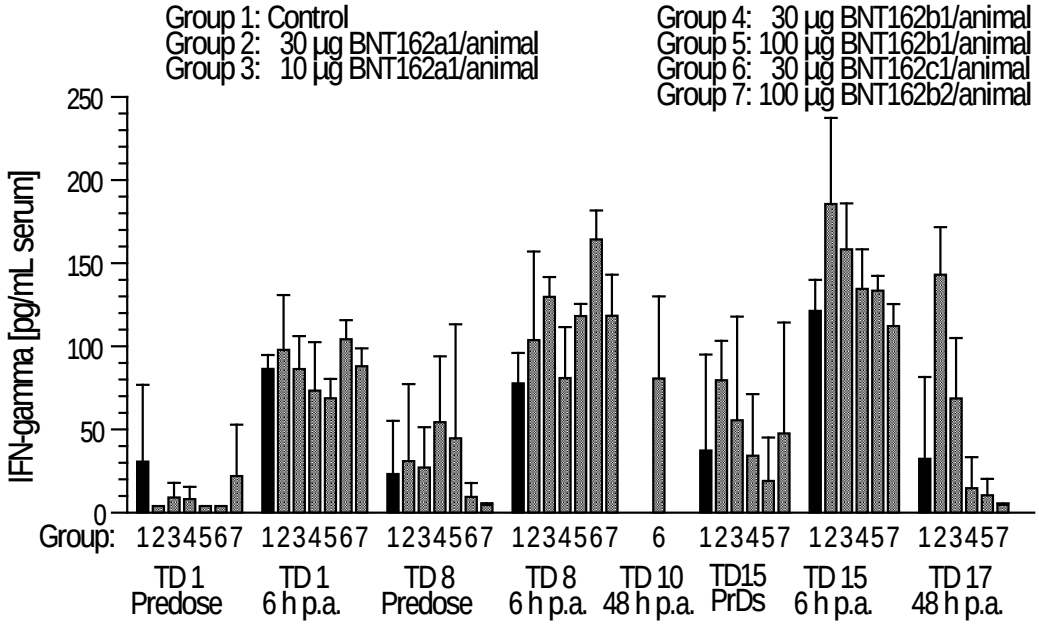


Figure 7-2 IFN-gamma levels in serum of female rats
mean values per group and standard deviation



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Figure 8-1 TNF-alpha levels in serum of male rats mean values per group and standard deviation

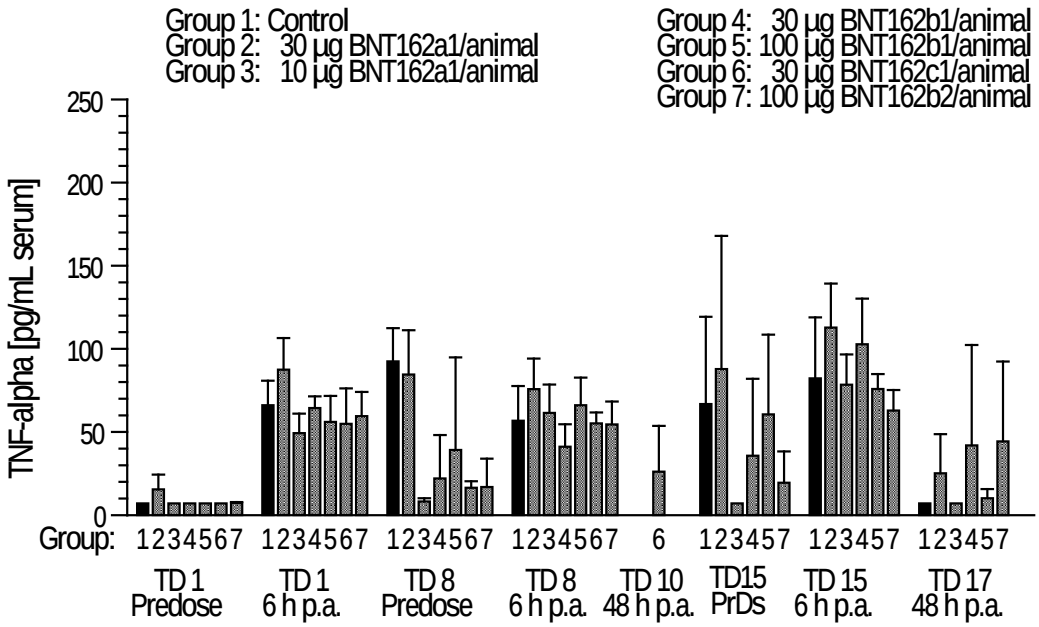
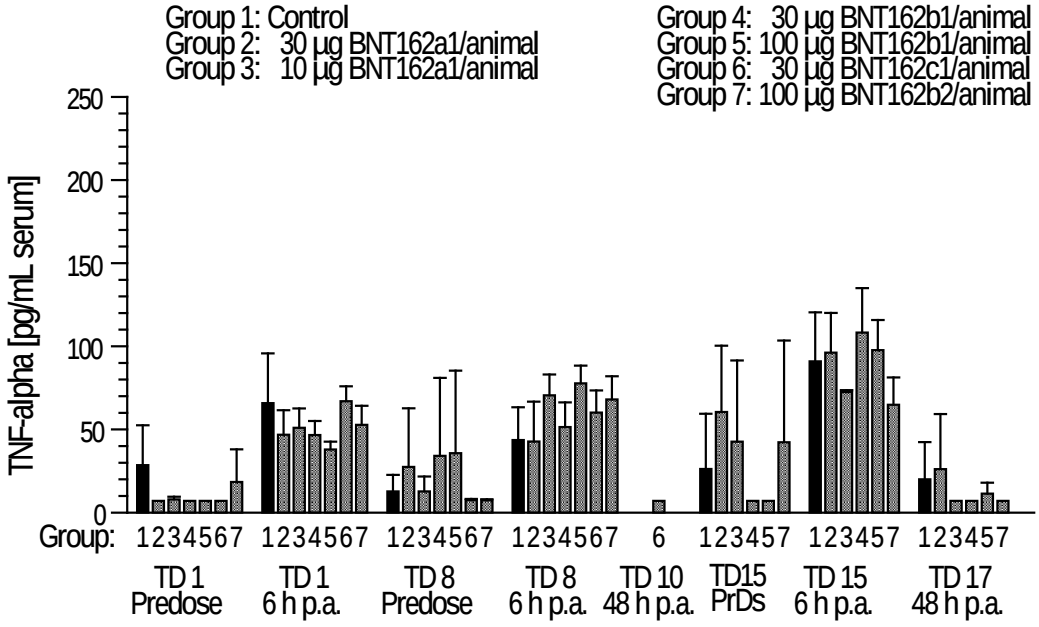


Figure 8-2 TNF-alpha levels in serum of female rats mean values per group and standard deviation



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Figure 9-1 IL-1beta levels in serum of male rats
mean values per group and standard deviation

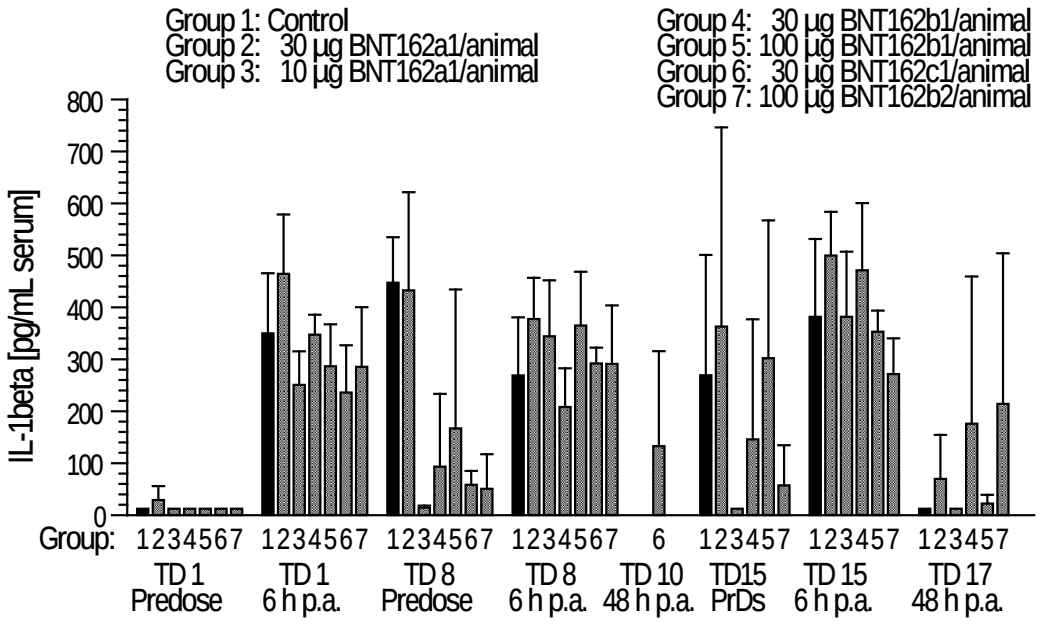
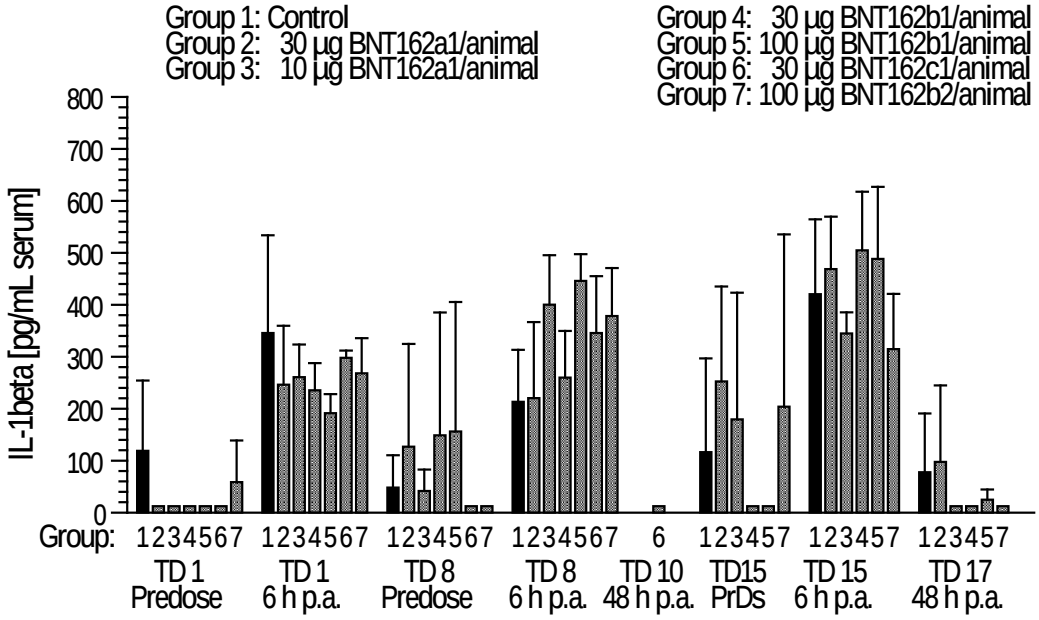


Figure 9-2 IL-1beta levels in serum of female rats
mean values per group and standard deviation



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Figure 10-1 IL-6 levels in serum of male rats
mean values per group and standard deviation

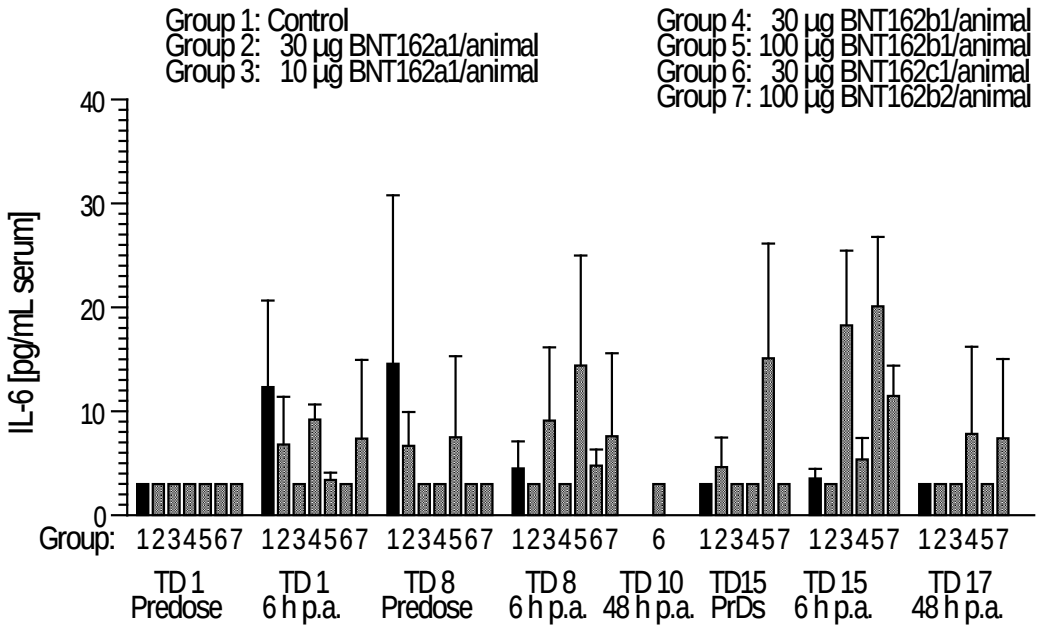
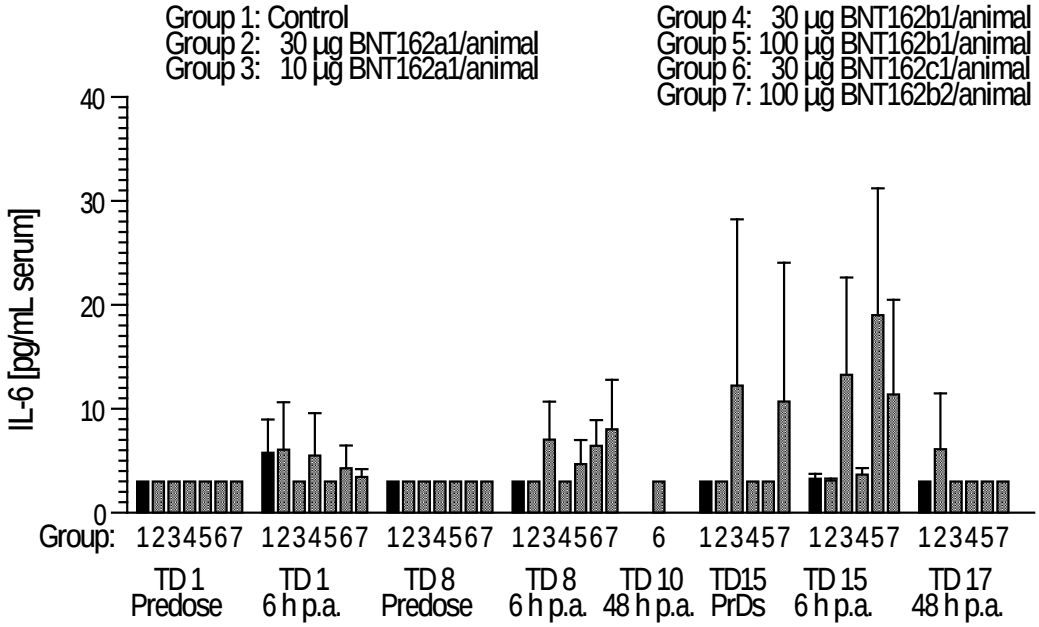


Figure 10-2 IL-6 levels in serum of female rats
mean values per group and standard deviation



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Figure 11-1 IL-10 levels in serum of male rats
mean values per group and standard deviation

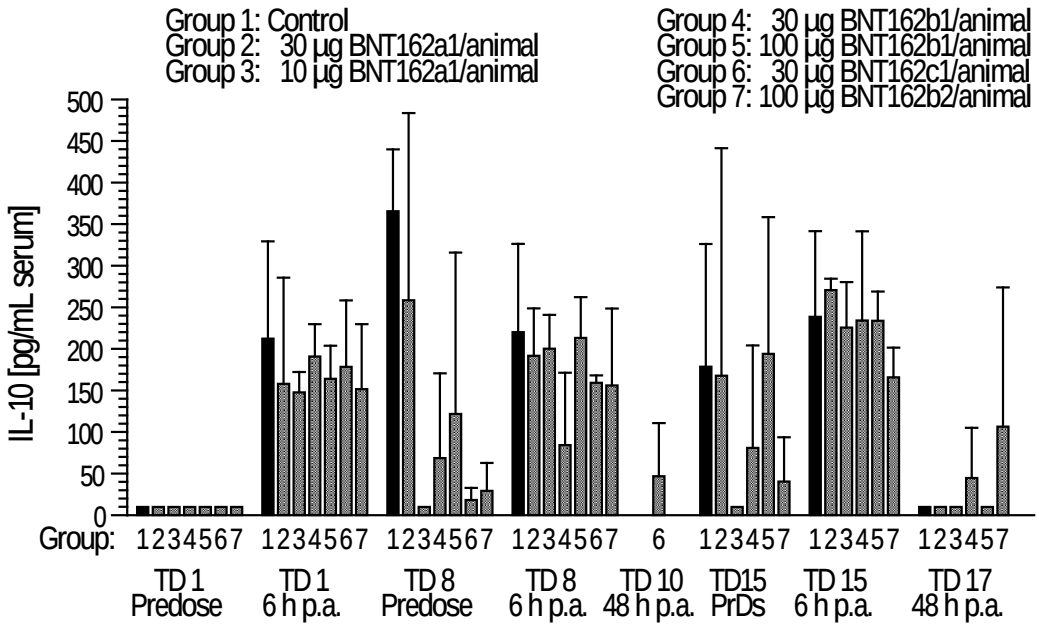
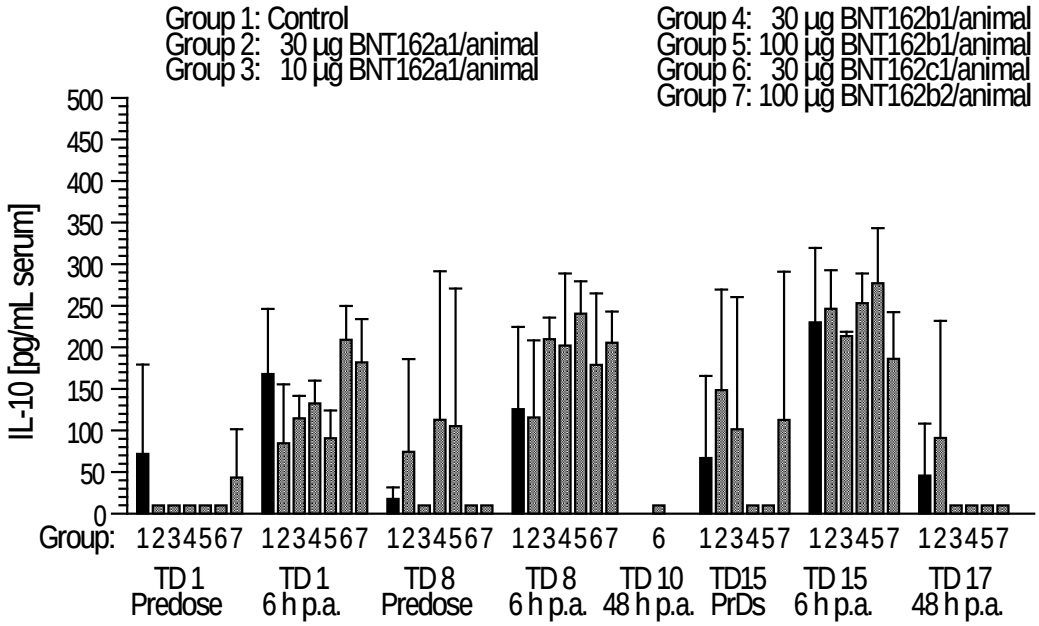


Figure 11-2 IL-10 levels in serum of female rats
mean values per group and standard deviation



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4.11 Urinalysis

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery period

Intramuscular treatment with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8 did not lead to any test item-related changes of the urinary parameters in the male and female animals compared to the respective control animals.

No test item-related changes were noted for the specific gravity, the pH value of the urine and the urine volume. The analyte concentrations of nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and haemoglobin were not influenced in a test item-related way in male and female animals. No test item-related changes were observed in the urine colour and the microscopically analysed urine sediments.

Text table 4-18: Statistically significant changes in urinary parameters considered not test item-related

Statistically significant changes in urinary parameters (refer to Table 10-1) in comparison to the control group considered not test item-related								
Urinary parameter	**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Specific gravity	4	3	30	m	17	+1.3	$p \leq 0.01$	A
				f	17	+2.0	$p \leq 0.01$	A
	5	3	100	m	17	+1.4	$p \leq 0.01$	A
	7	4	100	m	17	+1.5	$p \leq 0.01$	A
Urine volume	4	3	30	m	17	-32.7	$p \leq 0.01$	B
	5	3	100	m	17	-26.2	$p \leq 0.05$	B
	7	4	100	m	17	-30.9	$p \leq 0.01$	B

Test item 3: BNT162b1 - Groups 4 and 5
Test item 4: BNT162b2 - Group 7

m male
f female

A Change is within the limits of normal biological variation (with regard to the range covered by the control group) and without toxicological relevance.
B Change is due to the relative high or low value noted for the control group.

Group mean values of urinary parameters are presented in Table 10-1 (Urinalysis - Summary), individual data are listed in Table 10-2 (Urinalysis - Individual Data).

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4.12 Immunogenicity assessment

The serum samples prepared from the blood collected at terminal dissection and recovery dissection (see Section 3.8.8) were analysed by BioNTech SE, Germany, under the responsibility of the Sponsor. A summary from the analytical report forwarded to (b) (4) is given following below.

'*The recorded data demonstrates that all BNT162 vaccine candidates elicited a SARS-CoV-2-S protein specific antibody response directed against the S1 domain and the RBD sub-domain. The antibody response induced by the BNT162c1 vaccine was low in extent and did not confer neutralization activity in most animals. The development of the BNT162c1 candidate was discontinued. For BNT162a1, BNT162b1 and BNT162b2 vaccines, antibody responses detected via ELISA increased over time and directly translated into neutralizing activity as seen in the VSV/SARS-CoV-2-S pseudovirus neutralization test. For those vaccine candidates, sera from animals with higher antigen-specific antibody titers also displayed more pronounced virus neutralization effect and, in case of modRNA based vaccines, BNT162b1 and BNT162b2, exceeded the upper limit of quantification of the assay.*'

For details, refer to the analytical report 'Immunogenicity Assessment of BNT162a1, BNT162b1, BNT162b2 and BNT162c1 in Rat Serum after Repeated Intramuscular Administration' provided by BioNTech SE, Germany, in Appendix 4.

4.13 Ophthalmological and auditory examinations

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Treatment period and recovery period

The ophthalmological examination did not reveal any changes of the eyes and the optic region for the male and female animals following intramuscular treatment with **10** or **30 µg BNT162a1/animal**, **30** or **100 µg BNT162b1/animal**, or **100 µg BNT162b2/animal** on test days 1, 8, and 15, or with **30 µg BNT162c1/animal** on test days 1 and 8 at the end of the treatment period and at the end of the recvorey period.

There was no indication of any impairment to the auditory acuity through any treatment.

See Table 11 (Ophthalmological Examination) and Table 12 (Auditory Examination) for listings of individual findings.

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4.14 Macroscopic *post mortem* findings

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Terminal sacrifice

Test item-related findings were noted for all test items and all dose levels in male and female animals as given in the text tables following below.

Text table 4-19: Incidences of test item-related macroscopic findings for the animals treated with BNT162a1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17 (refer to Table 13)				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation: - Injection site I and/or II thickened / indurated / (skin) incrusted	3/10	1/10	5/10	5/10
Injection site I (left): - Muscle(s) indurated / muscles thickened / indurated	7/10	8/10	10/10	10/10
Spleen: - Enlarged	5/10	2/10	2/10	4/10
Lymph node (iliac): - Enlarged	4/10	3/10	1/10	1/10

.../... Number of animals affected per number of animals examined.

Text table 4-20: Incidences of test item-related macroscopic findings for the animals treated with BNT162b1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17 (refer to Table 13)				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation: - Injection site I and/or II thickened	0/10	0/10	1/10	1/10
Injection site I and/or II (left/right): - Muscle(s) indurated / muscles thickened / indurated / enlarged	7/10	6/10	7/10	6/10
Spleen: - Enlarged	1/10	1/10	5/10	7/10
Lymph node (iliac or renal, left): - Enlarged	6/10	4/10	7/10	8/10

.../... Number of animals affected per number of animals examined.

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Text table 4-21: Incidences of test item-related macroscopic findings for the animals treated with BNT162c1 or BNT162b2

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 10 (group 6) or test day 17 (group 7) (refer to Table 13)				
Organ / Finding	**Group 6: 30 µg BNT162c1/animal**		**Group 7: 100 µg BNT162b2/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened and/or incrusted	9/10	9/10	1/10	1/10
Injection site I and/or II (left/right):				
- Muscle(s) indurated or jellied / thickened / indurated / enlarged	10/10	10/10	7/10	9/10
Spleen:				
- Enlarged	5/10	1/10	2/10	7/10
Lymph node (iliac or iliac/renal):				
- Enlarged	1/10	2/10	5/10	6/10
Sciatic nerve (left):				
- Adhered to injection site I	0/10	0/10	0/10	3/10

.../... Number of animals affected per number of animals examined.

All systemic changes noted macroscopically are interpreted to be due to inflammation at the injection site and/or immune activation.

Recovery sacrifice

All macroscopic findings noted at the injection sites and for the spleen had subsided in all animals of all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups)

Enlarged iliac lymph nodes were still noted for a few animals as follows:

Group 4 (30 µg BNT162b1/animal): One of 5 females.
Group 5 (100 µg BNT162b1/animal): All 5 males, 2 of 5 females.
Group 7 (100 µg BNT162b2/animal): One of 5 males, 3 of 5 females.

These findings are regarded to be related to the previous test item treatment.

Further findings in form of emphysematous lungs, a reddened thymus, an enlarged right testis, a dilated uterus, in some cases filled with a clear liquid, a prostate and seminal vesicles that were reduced in size, and enlarged adrenal glands were noted for individual male and female animals in the test item-treated groups and the control group at terminal sacrifice or at recovery sacrifice. Due to the isolated occurrence per finding, all of these findings are considered as spontaneous changes that are not test item-related.

The macroscopic findings of individual animals are listed in Table 13 (Macroscopic Post Mortem Findings).

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4.15 Organ weights

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Main study animals

In accordance with the macroscopic findings of enlarged spleens (see Section 4.11), increased relative and absolute spleen weights were noted for all test items at all dose levels in male and female animals as given in the text table following below.

Text table 4-22: Test item-related changes in spleen weights

Test item-related changes in spleen weights compared to the control group in % (test day 10/group 6, test day 17/groups 2 to 5 and 7, refer to Table 14-1 and Table 15-1)								
Organ weight	BNT162a1				BNT162b1			
	Group 3: 10 µg/animal		Group 2: 30 µg/animal		Group 4: 30 µg/animal		Group 5: 100 µg/animal	
	Males	Females	Males	Females	Males	Females	Males	Females
Rel.	+27.8**	+25.7	+39.6**	+67.4**	+22.3**	+23.8	+30.0**	+49.4**
Abs.	+28.8**	+23.4	+16.5	+58.2**	+13.5	+30.6*	+22.9**	+54.8**
Organ weight	Group 6: 30 µg BNT162c1/animal				Group 7: 100 µg BNT162b2/animal			
	Males		Females		Males		Females	
Rel.	↑		↑		+36.6**		+62.3**	
Abs.	↑		↑		+25.2**		+60.8**	

Rel. relative (to body weight)
Abs. absolute
*/** Statistically significant at $p \leq 0.05$ / $p \leq 0.01$ (based on numerical data, not on percent difference).
↑ Increase relative to study control range, but % difference not quantifiable due to lacking concurrent controls.

All other differences between any of the test item-treated groups 2 to 7 and the control group at the end of the treatment period (test day 10 for group 6, test day 17 for groups 2 to 5 and 7), or at the end of the recovery period (test day 31 for group 6, test day 38 for groups 2 to 5 and 7) are considered to be coincidental background changes within the normal range of biological variation.

Recovery period

The slightly increased spleen weights noted at the end of the treatment period for the male and female animals of all dose groups had subsided at the end of the recovery period. There were no noteworthy differences in the absolute and relative weights of any organ between the test item-treated animals and the control animals at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups).

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Statistically significant differences in organ weights compared to the control animals that are not considered to be test item-related are listed in the text table below.

Text table 4-23: Statistically significant organ weight changes considered not test item-related

Statistically significant differences in organ weights (refer to Table 14-1 and Table 15-1) in comparison to the control group considered not test item-related									
Organ		**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
Adrenal gland (left)	- rel.	2	1	30	m	17	+31.0	$p \leq 0.01$	A, D
						38	+23.0	$p \leq 0.05$	A
		7	4	100	m	17	+23.4	$p \leq 0.05$	A, D
	- abs.	2	1	30	m	38	+18.3	$p \leq 0.05$	A
					f	38	-19.3	$p \leq 0.01$	A, B
		3	1	10	f	38	-26.0	$p \leq 0.01$	A, B
		4	3	30	f	38	-19.6	$p \leq 0.05$	A, B
Adrenal gland (right)	- rel.	2	1	30	m	17	+38.6	$p \leq 0.01$	A, D
					f	38	-21.8	$p \leq 0.05$	A
		3	1	10	f	38	-23.9	$p \leq 0.05$	A
		4	3	30	f	38	-24.3	$p \leq 0.05$	A
		5	3	100	m	17	+28.0	$p \leq 0.05$	A, D
	- abs.	2	1	30	f	38	-23.5	$p \leq 0.01$	A, B
		3	1	10	f	38	-27.0	$p \leq 0.01$	A, B
		4	3	30	f	38	-25.6	$p \leq 0.01$	A, B
Brain	- rel.	2	1	30	m	17	+17.2	$p \leq 0.01$	A, D
Epididymis (left)	- rel.	3	1	10	m	17	+25.5	$p \leq 0.01$	A, D
		5	3	100	m	17	+23.6	$p \leq 0.05$	A, D
		7	4	100	m	17	+32.5	$p \leq 0.05$	A, D
	- abs.	3	1	10	m	17	+26.3	$p \leq 0.01$	A, C
		7	4	100	m	17	+21.2	$p \leq 0.05$	A, C
Epididymis (right)	- rel.	2	1	30	m	17	+26.2	$p \leq 0.01$	A, B, D
		3	1	10	m	17	+24.2	$p \leq 0.01$	A, B, D
		4	3	30	m	17	+18.7	$p \leq 0.05$	A, B, D
		5	3	100	m	17	+36.5	$p \leq 0.01$	A, B, D
		7	4	100	m	17	+33.9	$p \leq 0.01$	A, B, D
	- abs.	3	1	10	m	17	+25.1	$p \leq 0.01$	A, B, D
						38	+22.1	$p \leq 0.05$	A, C
		5	3	100	m	17	+28.6	$p \leq 0.01$	A, C
						38	+17.2	$p \leq 0.05$	A, C
		7	4	100	m	17	+22.7	$p \leq 0.05$	A, C

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Statistically significant differences in organ weights (refer to Table 14-1 and Table 15-1) in comparison to the control group considered not test item-related

Organ		Group	Test item no.#	Dose [µg/ animal]	Sex	Test day	Change [%]	Statistical significance	Reason
- Text table continued from previous page -									
Testis (left)	- rel.	2	1	30	m	17	+16.5	p ≤ 0.01	A, D
		7	4	100	m	17	+12.1	p ≤ 0.01	A
Testis (right	- rel.	2	1	30	m	17	+18.8	p ≤ 0.01	A, D
		7	4	100	m	17	+11.8	p ≤ 0.01	A
Heart	- rel.	2	1	30	m	17	+15.2	p ≤ 0.01	A, D
		7	4	100	m	17	+8.8	p ≤ 0.05	A
Kidney (left)	- rel.	2	1	30	m	17	+10.3	p ≤ 0.05	A, D
					f	17	+11.9	p ≤ 0.01	A, D
		5	3	100	m	17	+10.1	p ≤ 0.05	A, D
		7	4	100	f	17	+8.9	p ≤ 0.05	A, D
Kidney (right)	- rel.	2	1	30	f	17	+9.1	p ≤ 0.01	A, D
		7	4	100	f	17	+8.0	p ≤ 0.01	A, D
Liver	- rel.	2	1	30	f	17	+15.7	p ≤ 0.01	A, D
		3	1	10	f	38	-10.9	p ≤ 0.05	A
		4	3	30	f	17	+10.3	p ≤ 0.05	A
		5	3	100	f	17	+15.3	p ≤ 0.01	A, D
		7	4	100	f	17	+20.6	p ≤ 0.01	A, D
	- abs.	2	1	30	m	17	-18.7	p ≤ 0.01	A, D
		4	3	30	m	17	-10.0	p ≤ 0.01	A, D
					f	17	+15.8	p ≤ 0.01	A
		5	3	100	f	17	+20.6	p ≤ 0.01	A, C
		7	4	100	f	17	+19.2	p ≤ 0.01	A, C
Lungs	- rel.	2	1	30	m	17	+14.5	p ≤ 0.01	A, D
					f	17	+18.0	p ≤ 0.01	A, D
		3	1	10	f	17	+13.8	p ≤ 0.05	A, D
		7	4	100	f	17	+15.2	p ≤ 0.05	A, D
Lymph node (mesent.)	- rel.	5	3	100	m	38	+86.3	p ≤ 0.05	A, C
	- abs.	3	1	10	m	38	+74.6	p ≤ 0.05	A, C
		5	3	100	m	38	+85.7	p ≤ 0.05	A, C
Thyroid/Par. (left)	- rel.	2	1	30	m	17	+26.5	p ≤ 0.05	A, D
		4	3	30	f	17	-30.5	p ≤ 0.05	A, E
		5	3	100	f	17	-29.9	p ≤ 0.05	A, E
- Text table continued on the next page -									

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Statistically significant differences in organ weights (refer to Table 14-1 and Table 15-1) in comparison to the control group considered not test item-related									
Organ		**Group**	**Test item no.#**	**Dose [µg/ animal]**	**Sex**	**Test day**	**Change [%]**	**Statistical significance**	**Reason**
- Text table continued from previous page -									
Thymus	- rel.	7	4	100	m	17	-21.3	$p \leq 0.05$	A, D
	- abs.	7	4	100	m	17	-27.9	$p \leq 0.01$	A

m male
f female

rel. relative
abs. absolute

A Change is within normal range of biological variation, without toxicological relevance.
B Change is due to the relatively low or high value noted for the control group.
C Change is related to the older age of the animals.
D Change is due to the slightly lower body weights of the respective test item treated animals compared to the control animals.
E Change is due to the slightly higher body weights of the respective test item treated animals compared to the control animals.

Relative organ weights are listed in Table 14-1 (Relative Organ Weights - Summary) and Table 14-2 (Relative Organ Weights - Individual Data). Absolute organ weights are listed in Table 15-1 (Absolute Organ Weights - Summary) and Table 15-2 (Absolute Organ Weights - Individual Data).

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4.16 Histopathology

Terminal sacrifice

Test item-related microscopic findings at the end of dosing included inflammation at the injection site and surrounding tissues, increased cellularity of germinal centers and increased plasma cells in the draining (iliac) lymph node, increased cellularity (hematopoiesis) in the bone marrow and spleen, and vacuolation of hepatocytes in the portal regions. All microscopic findings were partially or fully recovered at the end of the 3 week recovery phase.

Test item-related injection site reactions were present in all groups and characterized by mostly moderate inflammation (up to marked) in males and moderate inflammation in females. The most severe findings were noted consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate oedema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. Injection site findings were partially recovered at the end of the 3-week recovery phase. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac). These findings were mostly recovered at the end of the 3-week recovery phase.

Test item-related findings in the draining (iliac) lymph node were characterized by increased cellularity of the follicular germinal centers and increased plasma cells (plasmacytosis) and were variably present in all groups.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen were present in all groups.

A test item-related vacuolation of hepatocytes in the portal regions of the liver was present in all groups.

Test item-related findings were noted for all test items and all dose levels in male and female animals as given in the text tables following on the next pages.

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Text table 4-24: Incidences of test item-related microscopic findings for the animals treated with BNT162a1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I (left):				
- Fibrosis intramuscular/interstitial	10/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	10/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	9/10**	9/10**	9/10**
- Oedema, subcutis	10/10**	9/10**	6/10*	10/10**
- Oedema intramuscular/interstitial	7/10**	8/10**	2/10	10/10**
- Oedema inter-/ perimuscular	10/10**	10/10**	7/10**	10/10**
- Hyperplasia, epidermis	9/10**	7/10**	10/10**	9/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	1/10	3/10	0/10
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	1/10	0/10	1/10
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	3/10	0/10	0/10
Lymph node (iliac):				
- Plasmacytosis	7/10**	7/10**	5/10*	3/10
- Inflammation	0/10	3/10	5/10*	6/10*
- Increased cellularity, germinal center	9/10	10/10**	9/10	8/10
Spleen:				
- Increased haematopoiesis	3/10	2/10	0/10	0/10
Liver				
- Vacuolation, hepatocellular, periportal	1/10	6/10*	1/10	10/10**

.../... number of animals affected per number of animals examined

* significantly different from control ($p \leq 0.05$)

** significantly different from control ($p \leq 0.01$)

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Text table 4-25: Incidences of test item-related microscopic findings for the animals treated with BNT162b1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	10/10**	10/10**	10/10**
- Oedema, subcutis	9/10**	10/10**	10/10**	10/10**
- Oedema intramuscular/interstitial	8/10**	9/10**	10/10**	10/10**
- Oedema inter-/ perimuscular	10/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	8/10**	10/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	1/10	4/10	7/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	4/10	6/10*
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	0/10	2/10	1/10
Lymph node (iliac):				
- Plasmacytosis	9/10**	8/10**	8/10**	10/10**
- Inflammation	0/10	0/10	5/10*	8/9**
- Increased cellularity, geminal center	10/10	8/10	10/10	10/10**
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	7/10**
Liver				
- Vacuolation, hepatocellular, periportal	0/10	10/10**	8/10**	10/10**

.../... number of animals affected per number of animals examined

* significantly different from control ($p \leq 0.05$)

** significantly different from control ($p \leq 0.01$)

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Text table 4-26: Incidences of test item-related microscopic findings for the animals treated with BNT162c1 and BNT162b2

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 10 (group 6) or test day 17 (group 7)				
Organ / Finding	BNT162c1		BNT162b2	
	Group 6: 30 µg/animal		Group 7: 100 µg/animal	
	Males	Females	Males	Females
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed	9/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	8/10**	9/10**	10/10**	10/10**
- Oedema, subcutis	9/10**	10/10**	10/10**	10/10**
- Oedema intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Oedema inter-/ perimuscular	9/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	10/10**	9/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	0/10	10/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	2/10	9/10**
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	4/10	2/10	0/10
Lymph node (iliac):				
- Plasmacytosis	6/10*	7/10**	10/10**	10/10**
- Inflammation	4/10	7/10**	9/10**	6/10*
- Increased cellularity, germinal center	10/10	10/10**	10/10	10/10**
Skeletal muscle:				
- Infiltration, lymphohistiogranulocyt.	0/10	0/10	5/10*	0/10
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	8/10**
Liver				
- Vacuolation, hepatocellular, periportal	1/10	10/10**	9/10**	10/10**

.../... number of animals affected per number of animals examined

* significantly different from control ($p \leq 0.05$)

** significantly different from control ($p \leq 0.01$)

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Recovery sacrifice

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland; skeletal muscle) and spleen were partially or completely recovered in all animals at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups). Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals, being less severe (minimal to mild) if not resolved; plasmacytosis in the iliac lymph node was less severe and present in fewer groups (30 or 100 µg BNT162b1/animal or 100 µg BNT162b2/animal) at the end of the 3-week recovery period, indicating partial or complete recovery.

The infiltration of macrophages in the iliac lymph nodes of previously treated recovery animals were regarded as consequence of phagocytosis relating to the inflammatory reactions at the injection sites.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen was fully recovered at the end of the 3-week recovery phase.

Test item-related vacuolation of hepatocytes in the portal regions of the liver was fully recovered at the end of the 3-week recovery phase.

The incidence and the severity of the remaining findings were markedly reduced compared to the main study animals.

The complete Histopathology Report is given in Section 6.

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5. TABLES

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 1: Control (2 × 100 µl Buffer/animal)

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
1	n/a	n/a	No signs of local intolerance
2	n/a	n/a	No signs of local intolerance
3	n/a	n/a	No signs of local intolerance
4	n/a	n/a	No signs of local intolerance
5	n/a	n/a	No signs of local intolerance
6	n/a	n/a	No signs of local intolerance
7	n/a	n/a	No signs of local intolerance
8	n/a	n/a	No signs of local intolerance
9	n/a	n/a	No signs of local intolerance
10	n/a	n/a	No signs of local intolerance

- *Group 1 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 1: Control (2 × 100 µl Buffer/animal)- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
11	n/a	n/a	No signs of local intolerance
12	n/a	n/a	No signs of local intolerance
13	n/a	n/a	No signs of local intolerance
14	n/a	n/a	No signs of local intolerance
15	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
11	n/a	n/a	No signs of local intolerance
12	n/a	n/a	No signs of local intolerance
13	n/a	n/a	No signs of local intolerance
14	n/a	n/a	No signs of local intolerance
15	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 2: 30 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
31	n/a	n/a	No signs of local intolerance
32	14	1	Eschar formation (injection site)
33	n/a	n/a	No signs of local intolerance
34	14	1	Eschar formation (injection site)
35	n/a	n/a	No signs of local intolerance
36	n/a	n/a	No signs of local intolerance
37	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
38	n/a	n/a	No signs of local intolerance
39	14	1	Eschar formation (injection site)
40	n/a	n/a	No signs of local intolerance

- *Group 2 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 2: 30 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
41	n/a	n/a	No signs of local intolerance
42	14	1	Eschar formation (injection site)
43	9, 10	2	Injection site appears to be painful
44	9	1	Injection site appears to be painful
45	9	1	Injection site appears to be painful

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
41	n/a	n/a	No signs of local intolerance
42	n/a	n/a	No signs of local intolerance
43	n/a	n/a	No signs of local intolerance
44	n/a	n/a	No signs of local intolerance
45	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 3: 10 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
61	n/a	n/a	No signs of local intolerance
62	n/a	n/a	No signs of local intolerance
63	n/a	n/a	No signs of local intolerance
64	n/a	n/a	No signs of local intolerance
65	n/a	n/a	No signs of local intolerance
66	n/a	n/a	No signs of local intolerance
67	n/a	n/a	No signs of local intolerance
68	n/a	n/a	No signs of local intolerance
69	n/a	n/a	No signs of local intolerance
70	n/a	n/a	No signs of local intolerance

- *Group 3 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 3: 10 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
71	n/a	n/a	No signs of local intolerance
72	n/a	n/a	No signs of local intolerance
73	n/a	n/a	No signs of local intolerance
74	n/a	n/a	No signs of local intolerance
75	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
71	n/a	n/a	No signs of local intolerance
72	n/a	n/a	No signs of local intolerance
73	n/a	n/a	No signs of local intolerance
74	n/a	n/a	No signs of local intolerance
75	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 4: 30 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
91	n/a	n/a	No signs of local intolerance
92	n/a	n/a	No signs of local intolerance
93	n/a	n/a	No signs of local intolerance
94	n/a	n/a	No signs of local intolerance
95	n/a	n/a	No signs of local intolerance
96	n/a	n/a	No signs of local intolerance
97	n/a	n/a	No signs of local intolerance
98	n/a	n/a	No signs of local intolerance
99	n/a	n/a	No signs of local intolerance
100	n/a	n/a	No signs of local intolerance

- *Group 4 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 4: 30 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
101	n/a	n/a	No signs of local intolerance
102	n/a	n/a	No signs of local intolerance
103	n/a	n/a	No signs of local intolerance
104	n/a	n/a	No signs of local intolerance
105	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
101	n/a	n/a	No signs of local intolerance
102	n/a	n/a	No signs of local intolerance
103	n/a	n/a	No signs of local intolerance
104	n/a	n/a	No signs of local intolerance
105	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 5: 100 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
121	n/a	n/a	No signs of local intolerance
122	n/a	n/a	No signs of local intolerance
123	n/a	n/a	No signs of local intolerance
124	n/a	n/a	No signs of local intolerance
125	n/a	n/a	No signs of local intolerance
126	n/a	n/a	No signs of local intolerance
127	n/a	n/a	No signs of local intolerance
128	n/a	n/a	No signs of local intolerance
129	n/a	n/a	No signs of local intolerance
130	n/a	n/a	No signs of local intolerance

- *Group 5 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 5: 100 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
131	n/a	n/a	No signs of local intolerance
132	n/a	n/a	No signs of local intolerance
133	n/a	n/a	No signs of local intolerance
134	n/a	n/a	No signs of local intolerance
135	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
131	n/a	n/a	No signs of local intolerance
132	n/a	n/a	No signs of local intolerance
133	n/a	n/a	No signs of local intolerance
134	n/a	n/a	No signs of local intolerance
135	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 6: 30 µg BNT162c1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
151	n/a	n/a	No signs of local intolerance
152	n/a	n/a	No signs of local intolerance
153	n/a	n/a	No signs of local intolerance
154	n/a	n/a	No signs of local intolerance
155	n/a	n/a	No signs of local intolerance
156	n/a	n/a	No signs of local intolerance
157	n/a	n/a	No signs of local intolerance
158	n/a	n/a	No signs of local intolerance
159	n/a	n/a	No signs of local intolerance
160	n/a	n/a	No signs of local intolerance

- *Group 6 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 6: 30 µg BNT162c1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
161	n/a	n/a	No signs of local intolerance
162	n/a	n/a	No signs of local intolerance
163	n/a	n/a	No signs of local intolerance
164	n/a	n/a	No signs of local intolerance
165	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
161	n/a	n/a	No signs of local intolerance
162	n/a	n/a	No signs of local intolerance
163	n/a	n/a	No signs of local intolerance
164	n/a	n/a	No signs of local intolerance
165	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 7: 100 µg BNT162b2/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
181	n/a	n/a	No signs of local intolerance
182	n/a	n/a	No signs of local intolerance
183	n/a	n/a	No signs of local intolerance
184	n/a	n/a	No signs of local intolerance
185	n/a	n/a	No signs of local intolerance
186	n/a	n/a	No signs of local intolerance
187	n/a	n/a	No signs of local intolerance
188	n/a	n/a	No signs of local intolerance
189	n/a	n/a	No signs of local intolerance
190	n/a	n/a	No signs of local intolerance

- *Group 7 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Male animals

Group 7: 100 µg BNT162b2/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
191	n/a	n/a	No signs of local intolerance
192	n/a	n/a	No signs of local intolerance
193	n/a	n/a	No signs of local intolerance
194	n/a	n/a	No signs of local intolerance
195	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
191	n/a	n/a	No signs of local intolerance
192	n/a	n/a	No signs of local intolerance
193	n/a	n/a	No signs of local intolerance
194	n/a	n/a	No signs of local intolerance
195	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 1: Control (2 × 100 µl Buffer/animal)

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
16	n/a	n/a	No signs of local intolerance
17	n/a	n/a	No signs of local intolerance
18	n/a	n/a	No signs of local intolerance
19	n/a	n/a	No signs of local intolerance
20	n/a	n/a	No signs of local intolerance
21	n/a	n/a	No signs of local intolerance
22	n/a	n/a	No signs of local intolerance
23	n/a	n/a	No signs of local intolerance
24	n/a	n/a	No signs of local intolerance
25	n/a	n/a	No signs of local intolerance

- *Group 1 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 1: Control (2 × 100 µl Buffer/animal)- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
26	n/a	n/a	No signs of local intolerance
27	n/a	n/a	No signs of local intolerance
28	n/a	n/a	No signs of local intolerance
29	n/a	n/a	No signs of local intolerance
30	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
26	n/a	n/a	No signs of local intolerance
27	n/a	n/a	No signs of local intolerance
28	n/a	n/a	No signs of local intolerance
29	n/a	n/a	No signs of local intolerance
30	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 2: 30 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
46	14	1	Eschar formation (injection site)
47	n/a	n/a	No signs of local intolerance
48	n/a	n/a	No signs of local intolerance
49	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
50	9	1	Injection site appears to be painful
51	9	1	Injection site appears to be painful
52	9	1	Injection site appears to be painful
53	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
54	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
55	9	1	Injection site appears to be painful

- *Group 2 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 2: 30 μg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
56	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)
57	9	1	Injection site appears to be painful
58	9	1	Injection site appears to be painful
59	9	1	Injection site appears to be painful
60	9	1	Injection site appears to be painful
	14	1	Eschar formation (injection site)

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
56	n/a	n/a	No signs of local intolerance
57	n/a	n/a	No signs of local intolerance
58	n/a	n/a	No signs of local intolerance
59	n/a	n/a	No signs of local intolerance
60	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 3: 10 µg BNT162a1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
76	n/a	n/a	No signs of local intolerance
77	n/a	n/a	No signs of local intolerance
78	n/a	n/a	No signs of local intolerance
79	n/a	n/a	No signs of local intolerance
80	n/a	n/a	No signs of local intolerance
81	n/a	n/a	No signs of local intolerance
82	n/a	n/a	No signs of local intolerance
83	n/a	n/a	No signs of local intolerance
84	n/a	n/a	No signs of local intolerance
85	n/a	n/a	No signs of local intolerance

- *Group 3 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 3: 10 µg BNT162a1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
86	n/a	n/a	No signs of local intolerance
87	n/a	n/a	No signs of local intolerance
88	n/a	n/a	No signs of local intolerance
89	n/a	n/a	No signs of local intolerance
90	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
86	n/a	n/a	No signs of local intolerance
87	n/a	n/a	No signs of local intolerance
88	n/a	n/a	No signs of local intolerance
89	n/a	n/a	No signs of local intolerance
90	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 4: 30 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
106	n/a	n/a	No signs of local intolerance
107	n/a	n/a	No signs of local intolerance
108	n/a	n/a	No signs of local intolerance
109	n/a	n/a	No signs of local intolerance
110	n/a	n/a	No signs of local intolerance
111	n/a	n/a	No signs of local intolerance
112	n/a	n/a	No signs of local intolerance
113	n/a	n/a	No signs of local intolerance
114	n/a	n/a	No signs of local intolerance
115	n/a	n/a	No signs of local intolerance

- *Group 4 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 4: 30 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
116	n/a	n/a	No signs of local intolerance
117	n/a	n/a	No signs of local intolerance
118	n/a	n/a	No signs of local intolerance
119	n/a	n/a	No signs of local intolerance
120	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
116	n/a	n/a	No signs of local intolerance
117	n/a	n/a	No signs of local intolerance
118	n/a	n/a	No signs of local intolerance
119	n/a	n/a	No signs of local intolerance
120	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 5: 100 µg BNT162b1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
136	n/a	n/a	No signs of local intolerance
137	n/a	n/a	No signs of local intolerance
138	n/a	n/a	No signs of local intolerance
139	n/a	n/a	No signs of local intolerance
140	n/a	n/a	No signs of local intolerance
141	n/a	n/a	No signs of local intolerance
142	n/a	n/a	No signs of local intolerance
143	n/a	n/a	No signs of local intolerance
144	n/a	n/a	No signs of local intolerance
145	n/a	n/a	No signs of local intolerance

- *Group 5 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 5: 100 µg BNT162b1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
146	n/a	n/a	No signs of local intolerance
147	n/a	n/a	No signs of local intolerance
148	n/a	n/a	No signs of local intolerance
149	n/a	n/a	No signs of local intolerance
150	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
146	n/a	n/a	No signs of local intolerance
147	n/a	n/a	No signs of local intolerance
148	n/a	n/a	No signs of local intolerance
149	n/a	n/a	No signs of local intolerance
150	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 6: 30 µg BNT162c1/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
166	n/a	n/a	No signs of local intolerance
167	n/a	n/a	No signs of local intolerance
168	n/a	n/a	No signs of local intolerance
169	n/a	n/a	No signs of local intolerance
170	n/a	n/a	No signs of local intolerance
171	n/a	n/a	No signs of local intolerance
172	n/a	n/a	No signs of local intolerance
173	n/a	n/a	No signs of local intolerance
174	n/a	n/a	No signs of local intolerance
175	n/a	n/a	No signs of local intolerance

- *Group 6 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 6: 30 µg BNT162c1/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
176	n/a	n/a	No signs of local intolerance
177	n/a	n/a	No signs of local intolerance
178	n/a	n/a	No signs of local intolerance
179	n/a	n/a	No signs of local intolerance
180	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
176	n/a	n/a	No signs of local intolerance
177	n/a	n/a	No signs of local intolerance
178	n/a	n/a	No signs of local intolerance
179	n/a	n/a	No signs of local intolerance
180	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 7: 100 µg BNT162b2/animal

Treatment period

Animal no.	Observed on test day	Total number of days	Observation
196	n/a	n/a	No signs of local intolerance
197	n/a	n/a	No signs of local intolerance
198	n/a	n/a	No signs of local intolerance
199	n/a	n/a	No signs of local intolerance
200	n/a	n/a	No signs of local intolerance
201	n/a	n/a	No signs of local intolerance
202	n/a	n/a	No signs of local intolerance
203	n/a	n/a	No signs of local intolerance
204	n/a	n/a	No signs of local intolerance
205	n/a	n/a	No signs of local intolerance

- *Group 7 continued on the next page.* -

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins
TABLE 1-1 Local Tolerance (General Observation) - Individual Data Rat

Female animals

Group 7: 100 µg BNT162b2/animal- continued

Treatment period *(continued)*

Animal no.	Observed on test day	Total number of days	Observation
206	n/a	n/a	No signs of local intolerance
207	n/a	n/a	No signs of local intolerance
208	n/a	n/a	No signs of local intolerance
209	n/a	n/a	No signs of local intolerance
210	n/a	n/a	No signs of local intolerance

Recovery period

Animal no.	Observed on test day	Total number of days	Observation
206	n/a	n/a	No signs of local intolerance
207	n/a	n/a	No signs of local intolerance
208	n/a	n/a	No signs of local intolerance
209	n/a	n/a	No signs of local intolerance
210	n/a	n/a	No signs of local intolerance

n/a = not applicable

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Males (1) E	Oe	I/H	F	(2) E	Oe	I/H	F	(3) E	Oe	I/H	F	(4) E	Oe	I/H	F	(5) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Males (6) E	Oe	I/H	F	(7) E	Oe	I/H	F	(8) E	Oe	I/H	F	(9) E	Oe	I/H	F	(10) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Males (11) E	Oe	I/H	F	(12) E	Oe	I/H	F	(13) E	Oe	I/H	F	(14) E	Oe	I/H	F	(15) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	3/2	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
Recovery period																					
17 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Females (16) E	Oe	I/H	F	(17) E	Oe	I/H	F	(18) E	Oe	I/H	F	(19) E	Oe	I/H	F	(20) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/…:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Females (21) E	Oe	I/H	F	(22) E	Oe	I/H	F	(23) E	Oe	I/H	F	(24) E	Oe	I/H	F	(25) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/…:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 1: Control (2 × 100 µl Buffer/animal)

Test day (time p.a.)	Inj.	Animal no. - Females (26) E	Oe	I/H	F	(27) E	Oe	I/H	F	(28) E	Oe	I/H	F	(29) E	Oe	I/H	F	(30) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	3/2	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
Recovery period																					
17 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/…:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (31) E	Oe	I/H	F	(32) E	Oe	I/H	F	(33) E	Oe	I/H	F	(34) E	Oe	I/H	F	(35) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	2	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	2	0	-
5 (96 h)		0	0	0	S	1	0	0	S	0	0	0	S	0	0	0	S	1	1	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1	0	-	1	2	0	-	1	2	0	-	0	2	0	-
10 (48 h)		0	0	0	-	2	1	0	-	1	2	0	-	2	2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	1	0	0	-	1	1	0	-	1	1	0	-	0	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (36) E	Oe	I/H	F	(37) E	Oe	I/H	F	(38) E	Oe	I/H	F	(39) E	Oe	I/H	F	(40) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	2	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-
5 (96 h)		0	0	0	S	1	0	0	S	0	1	0	S	1	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	0	3	0	-	1	2	0	-	0	1	0	-	0	2	0	-
10 (48 h)		1	2	0	-	1	3	0	-	0	1	0	-	1	1	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
		S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (41) E	Oe	I/H	F	(42) E	Oe	I/H	F	(43) E	Oe	I/H	F	(44) E	Oe	I/H	F	(45) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	0	0	-	0	0	0	-
5 (96 h)		1	0	0	S	1	1	0	S	1	0	0	S	0	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	1	0	-	0	2	0	-	1	3	0	-	0	3	0	-	0	3	0	-
10 (48 h)		0	3	0	-	1	2	0	-	1	3	0	-	0	3/2	0	-	1	2	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	1	2	0	-	0	1	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	1	0	-	0	0	0	-	1	2	0	-	0	2	0	-	1	2	0	-
19 (96 h)		4	0	0	-	4	0	0	-	4	2	0	-	4	1	0	-	4	2	0	-
21 (144 h)		1	0	0	-	1	0	0	-	1	1	0	-	0	0	0	-	0	0	0	-
23 (192 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
27 (288 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		1	0	0	T	1	0	0	T	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		1	0	0	T	1	0	0	T	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		1	0	0	T	1	0	0	T	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin
T: Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (46) E	Oe	I/H	F	(47) E	Oe	I/H	F	(48) E	Oe	I/H	F	(49) E	Oe	I/H	F	(50) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
5 (96 h)		0	0	0	S	1	0	0	S	1	0	0	S	0	0	0	S	0	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	3	0	-
10 (48 h)		0	2	0	-	1	0	0	-	1	2	0	-	1	3	0	-	0	2	0	-
12 (96 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (51) E	Oe	I/H	F	(52) E	Oe	I/H	F	(53) E	Oe	I/H	F	(54) E	Oe	I/H	F	(55) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		1	1	0	S	1	1	0	S	1	0	0	S	0	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	1	2	0	-	0	2	0	-	1	3	0	-	1	2	0	-
10 (48 h)		1	2	0	-	1	3	0	-	1	3	0	-	1	3	0	-	1	3	0	-
12 (96 h)		0	0	0	-	0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	1	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 2: 30 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (56) E	Oe	I/H	F	(57) E	Oe	I/H	F	(58) E	Oe	I/H	F	(59) E	Oe	I/H	F	(60) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	2	0	-	0	0	0	-	0	2	0	-	0	2	0	-	0	1	0	-
5 (96 h)		0	0	0	S	0	0	0	S	0	1	0	S	0	0	0	S	1	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
10 (48 h)		1	2	0	-	0	2	0	-	0	3	0	-	0	3/2	0	-	2	2	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-	1	1	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	1	0	-	0	1	0	-	0	1	0	-	1	2	0	-
Recovery period																					
17 (48 h)		1	2	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-
19 (96 h)		4	2	0	-	4	2	0	-	4	2	0	-	4	1	0	-	4	0/1	0	-
21 (144 h)		1	0	0	-	0	0	0	-	2	0	0	-	2	0	0	-	2	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	1	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	4	1	0	-	4	0	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	4	1	0	-	4	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	2	0	0	-	2	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	T	0	0	0	T	0	0	0	T
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	T

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin
		T:	Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (61) E	Oe	I/H	F	(62) E	Oe	I/H	F	(63) E	Oe	I/H	F	(64) E	Oe	I/H	F	(65) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	3	0	-	0	3	0	-	0	2	0	-	0	3	0	-
12 (96 h)		0	2	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (66) E	Oe	I/H	F	(67) E	Oe	I/H	F	(68) E	Oe	I/H	F	(69) E	Oe	I/H	F	(70) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	2	0	-	0	2	0	-	0	3	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	4	1	0	-	0	0	0	-	4	0	2	-	0	1	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	1	1	0	-	0	2	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (71) E	Oe	I/H	F	(72) E	Oe	I/H	F	(73) E	Oe	I/H	F	(74) E	Oe	I/H	F	(75) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	1	0	-
Recovery period																					
17 (48 h)		1	0	0	-	1	0	1	-	1	1	0	-	0	2	0	-	0	2	0	-
19 (96 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	2	0	-	0	0	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	2	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	3	-	0	0	0	-
25 (240 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (76) E	Oe	I/H	F	(77) E	Oe	I/H	F	(78) E	Oe	I/H	F	(79) E	Oe	I/H	F	(80) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	0	0	-	0	1	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	4	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	1	2	0	-	0	2	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (81) E	Oe	I/H	F	(82) E	Oe	I/H	F	(83) E	Oe	I/H	F	(84) E	Oe	I/H	F	(85) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	3	0	-	0	3	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 3: 10 µg BNT162a1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (86) E	Oe	I/H	F	(87) E	Oe	I/H	F	(88) E	Oe	I/H	F	(89) E	Oe	I/H	F	(90) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-
Recovery period																					
17 (48 h)		1	1	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
27 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (91) E	Oe	I/H	F	(92) E	Oe	I/H	F	(93) E	Oe	I/H	F	(94) E	Oe	I/H	F	(95) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	2	0	-	0	1	0	-	0	2	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	2	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (96) E	Oe	I/H	F	(97) E	Oe	I/H	F	(98) E	Oe	I/H	F	(99) E	Oe	I/H	F	(100) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	S
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	2	0	-	0	1	0	-	0	1	0	-	1	0	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	1	1	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (101) E	Oe	I/H	F	(102) E	Oe	I/H	F	(103) E	Oe	I/H	F	(104) E	Oe	I/H	F	(105) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	S	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	1	2	0	-	1	1	0	-	0	1	0	-
10 (48 h)		0	0	0	-	0	0	0	-	1	1	0	-	0	3/2	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	1	0	-	0	2	0	-	1	2	0	-	0	1	0	-	0	2	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
27 (288 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	2	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	1	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	1	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin
T: Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (106) E	Oe	I/H	F	(107) E	Oe	I/H	F	(108) E	Oe	I/H	F	(109) E	Oe	I/H	F	(110) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	2	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	2	0	-	0	0	0	-
5 (96 h)		0	0	0	S	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		1	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	2	0	-	1	2	0	-	0	1	0	-	0	2	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (111) E	Oe	I/H	F	(112) E	Oe	I/H	F	(113) E	Oe	I/H	F	(114) E	Oe	I/H	F	(115) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	S	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	1	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
		S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 4: 30 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (116) E	Oe	I/H	F	(117) E	Oe	I/H	F	(118) E	Oe	I/H	F	(119) E	Oe	I/H	F	(120) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	2	0	-	0	0	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-	0	2	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	1	0	-	0	1	0	-
10 (48 h)		0	1	0	-	0	1	0	-	0	1	0	-	1	3/2	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-
Recovery period																					
17 (48 h)		0	1	0	-	0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-
19 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
21 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
27 (288 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.: Injection (i.m.)
X/...: Denotes day of injection/number of injection sites
E: Erythema (grading: see right)
Oe: Oedema (grading: see Section 3.8.3)
I/H: Induration/hardening (by palpation; grading: see Section 3.8.3)
F: Other findings (see right)

0: No finding
1: Very slight finding (barely perceptible)
2: Well-defined finding
3: Moderate to severe finding
4: Severe finding
-: No other finding
S: Scabby skin
T: Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (121) E	Oe	I/H	F	(122) E	Oe	I/H	F	(123) E	Oe	I/H	F	(124) E	Oe	I/H	F	(125) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0/1	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1/0	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	2/3	0	-	0	2	0	-	0	2	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (126) E	Oe	I/H	F	(127) E	Oe	I/H	F	(128) E	Oe	I/H	F	(129) E	Oe	I/H	F	(130) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1/0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1/0	0	-	0	0	0	-	0	1	0	-	0	1/0	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	3	0	-	0	3/2	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2/3	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (131) E	Oe	I/H	F	(132) E	Oe	I/H	F	(133) E	Oe	I/H	F	(134) E	Oe	I/H	F	(135) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	1/0	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	2	0	-	0	3/2	0	-	0	3	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	2/3	0	-	0	2	0	-	0	3	0	-	0	3/2	0	-	0	3	0	-
19 (96 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1/2	0	-
27 (288 h)		0	1	0	-	0	0	0	-	0	0/1	0	-	0	1	0	-	0	1	0	-
29 (336 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	1/0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (136) E	Oe	I/H	F	(137) E	Oe	I/H	F	(138) E	Oe	I/H	F	(139) E	Oe	I/H	F	(140) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		1	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0/1	0/1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	2/3	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (141) E	Oe	I/H	F	(142) E	Oe	I/H	F	(143) E	Oe	I/H	F	(144) E	Oe	I/H	F	(145) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	0	0	-	1/0	1/0	0	-	0	0	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	1/0	0	-	0	1/0	0	-	0	1	0	-
10 (48 h)		0	3	0	-	0	3/2	0	-	0	3	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2/3	0	-	1/0	2	0	-	0	3	0	-	0	2	0	-	0	2	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 5: 100 µg BNT162b1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (146) E	Oe	I/H	F	(147) E	Oe	I/H	F	(148) E	Oe	I/H	F	(149) E	Oe	I/H	F	(150) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-
3 (48 h)		0	1/0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	3/2	0	-	0	3/2	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
Recovery period																					
17 (48 h)		0	2	0	-	0	2	0	-	0	2	0	-	0	3/2	0	-	0	2	0	-
19 (96 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1/2	0	-	0	1	0	-	0	1	0	-	0	1/0	0	-	0	1	0	-
27 (288 h)		0	0/1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
35 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
37 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (151) E	Oe	I/H	F	(152) E	Oe	I/H	F	(153) E	Oe	I/H	F	(154) E	Oe	I/H	F	(155) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	0	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (156) E	Oe	I/H	F	(157) E	Oe	I/H	F	(158) E	Oe	I/H	F	(159) E	Oe	I/H	F	(160) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Males (161) E	Oe	I/H	F	(162) E	Oe	I/H	F	(163) E	Oe	I/H	F	(164) E	Oe	I/H	F	(165) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-
5 (96 h)		0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-
Recovery period																					
10 (48 h)		0	3	0	-	0	4	0	-	0	4	0	-	0	3	0	-	0	3	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	4	0	0	-	4	0	0	-	4	0	0	-	4	0	0	-
16 (192 h)		0	0	0	-	0	2	0	-	0	0	0	-	0	0	0	-	0	0	0	-
18 (240 h)		0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
20 (288 h)		0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
22 (336 h)		0	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
24 (384 h)		0	0	0	-	4	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-
26 (432 h)		0	0	0	-	1	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-
28 (480 h)		0	0	0	-	1	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-
30 (528 h)		0	0	0	-	1	0	0	C	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	C:	Incrusted wound / Scar tissue

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (166) E	Oe	I/H	F	(167) E	Oe	I/H	F	(168) E	Oe	I/H	F	(169) E	Oe	I/H	F	(170) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	1	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (171) E	Oe	I/H	F	(172) E	Oe	I/H	F	(173) E	Oe	I/H	F	(174) E	Oe	I/H	F	(175) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-	0	2	0	-
5 (96 h)		0	0	0	-	0	1	0	-	0	0	0	-	0	0	0	-	1	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 6: 30 µg BNT162c1/animal

Test day (time p.a.)	Inj.	Animal no. - Females (176) E	Oe	I/H	F	(177) E	Oe	I/H	F	(178) E	Oe	I/H	F	(179) E	Oe	I/H	F	(180) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
3 (48 h)		0	1	0	-	0	0	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	1	0	0	-	1	1	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/1	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	0	0	-	0	1	0	-
Recovery period																					
10 (48 h)		0	3	0	-	0	2	0	-	0	3	0	-	0	3	0	-	0	3	0	-
12 (96 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	1	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-
16 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
18 (240 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
20 (288 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
22 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
24 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
26 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
28 (480 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
30 (528 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Males (181) E	Oe	I/H	F	(182) E	Oe	I/H	F	(183) E	Oe	I/H	F	(184) E	Oe	I/H	F	(185) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	0/1	0	-	0	0/1	0	-	0	1	0	-	0	0/1	0	-
3 (48 h)		0	1	0	-	0	0/1	0	-	0	1	0	-	0	1	0	-	0	1	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-
10 (48 h)		0	3	0	-	0	3	0	-	0	3/2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	2	0	-	0	3	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Males (186) E	Oe	I/H	F	(187) E	Oe	I/H	F	(188) E	Oe	I/H	F	(189) E	Oe	I/H	F	(190) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1/0	0	-	0	1/0	0	-	0	1/0	0	-	0	1/0	0	-
3 (48 h)		0	0/1	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1/0	0	-	0	1/0	0	-	0	1/0	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	3/2	0	-	0	2	0	-	0	3	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	4	0	0	-	4	0	0	-	4	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	3	0	-	0	3	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Males (191) E	Oe	I/H	F	(192) E	Oe	I/H	F	(193) E	Oe	I/H	F	(194) E	Oe	I/H	F	(195) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1	0	-	0	1	0	-	0	0	0	-	0	0/1	0	-	0	1/0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	1	0	-
10 (48 h)		0	2	0	-	0	3	0	-	0	3/2	0	-	0	3/2	0	-	0	2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	3/4	0	-	0	3	0	-	0	3/4	0	-
Recovery period																					
17 (48 h)		1/0	3/2	0	-	0	3	0	-	0	3	0	-	0	2/3	0	-	0	2	0	-
19 (96 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
21 (144 h)		0	1	0	-	0	2	0	-	0	1	0	-	0	2	0	-	0	1	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1/2	0	-	0	1/2	0	-	0	2	0	-	0	1/2	0	-	0	1	0	-
27 (288 h)		0	1	0	-	0	1/2	0	-	0	2	0	-	0	1/0	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding noted at left/right administration site (if applicable and different severities were noted)		

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Females (196) E	Oe	I/H	F	(197) E	Oe	I/H	F	(198) E	Oe	I/H	F	(199) E	Oe	I/H	F	(200) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1/0	0	-	0	0/1	0	-	0	0	0	-	0	1/0	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0/1	0	-	0	0	0	-	0	0	0	-	0	1/0	0	-	0	1	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	1	0	-	0	1	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	4/0	0	0	-	4	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	2	0	-	0	2/3	0	-	0	2/3	0	-	0	3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding at left/right administration site, if different (if applicable and different severities were noted)	S:	Scabby skin

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Three LNP-Formulated RNA Platforms encoding for Viral Proteins

TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Females (201) E	Oe	I/H	F	(202) E	Oe	I/H	F	(203) E	Oe	I/H	F	(204) E	Oe	I/H	F	(205) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	0	0	-	0	1	0	-	0	1	0	-	0	0/1	0	-	0	1	0	-
3 (48 h)		0	0	0	-	0	0	0	-	0	1/0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	1/0	0	-	0	0	0	-	0	0/1	0	-	0	0	0	-	0	0	0	-
10 (48 h)		0	2	0	-	0	2	0	-	0	3/2	0	-	0	3	0	-	0	1	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		4	0	0	-	4	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3	0	-	0	3	0	-	0	2	0	-	0	3	0	-	0	2/3	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding at left/right administration site, if different (if applicable and different severities were noted)	S:	Scabby skin

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TABLE 1-2 Local Tolerance - Erythema, Oedema, Induration/Hardening Rat

Assessment of injection sites based on DRAIZE

Group 7: 100 µg BNT162b2/animal

Test day (time p.a.)	Inj.	Animal no. - Females (206) E	Oe	I/H	F	(207) E	Oe	I/H	F	(208) E	Oe	I/H	F	(209) E	Oe	I/H	F	(210) E	Oe	I/H	F
Treatment period																					
1 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
2 (24 h)		0	1/0	0	-	0	1	0	-	0	1/0	0	-	0	1	0	-	0	0	0	-
3 (48 h)		0	0	0	-	0	0/1	0	-	0	0	0	-	0	0	0	-	0	0	0	-
5 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	1	0	0	-	0	0	0	-
7 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
8 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
9 (24 h)		0	0	0	-	0	1/0	0	-	0	0	0	-	0	1	0	-	0	0/1	0	-
10 (48 h)		0	3	0	-	0	2	0	-	0	2/1	0	-	0	3/2	0	-	0	3/2	0	-
12 (96 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
14 (144 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	4	0	0	-
15 (4 h)	X/2	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
16 (24 h)		0	3/4	0	-	0	3	0	-	0	2/3	0	-	0	3	0	-	0	3	0	-
Recovery period																					
17 (48 h)		1/0	2/3	0	-	0	1/2	0	-	0	1	0	-	1/0	2	0	-	0	2	0	-
19 (96 h)		0	2	0	-	0	0	0	-	0	0/1	0	-	0	2/1	0	-	0	2/1	0	-
21 (144 h)		0	1	0	-	0	0	0	-	0	0/1	0	-	0	2/1	0	-	0	2/1	0	-
23 (192 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
25 (240 h)		0	1	0	-	0	1	0	-	0	1	0	-	0	1/2	0	-	0	1/2	0	-
27 (288 h)		0	1	0	-	0	0/1	0	-	0	1	0	-	0	1/2	0	-	0	1	0	-
29 (336 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
31 (384 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-
33 (432 h)		0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-	0	0	0	-

Inj.:	Injection (i.m.)	0:	No finding
X/...:	Denotes day of injection/number of injection sites	1:	Very slight finding (barely perceptible)
E:	Erythema (grading: see right)	2:	Well-defined finding
Oe:	Oedema (grading: see Section 3.8.3)	3:	Moderate to severe finding
I/H:	Induration/hardening (by palpation; grading: see Section 3.8.3)	4:	Severe finding
F:	Other findings (see right)	-:	No other finding
.../...:	Finding at left/right administration site, if different (if applicable and different severities were noted)		

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TABLE 2-1 Clinical Signs - Systemic Tolerance Rat
- Summary -

Observation Type: All Types Sex: Male From Day 1 (Start Date) to 38 (Start Date)	Group 1: Control	Group 2: 30 µg/ animal BNT162a1	Group 3: 10 µg/ animal BNT162a1	Group 4: 30 µg/ animal BNT162b1	Group 5: 100 µg/ animal BNT162b1	Group 6: 30 µg/ animal BNT162c1	Group 7: 100 µg/ animal BNT162b2
Normal							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	1 - 38	1 - 38	1 - 38	1 - 38	1 - 38	1 - 31	1 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	360	360	360	360	360	255	360
Scheduled Removal (Terminal)							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	17 - 38	17 - 38	17 - 38	17 - 38	17 - 38	10 - 31	17 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	15	15	15	15	15	15	15

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TABLE 2-1 Clinical Signs - Systemic Tolerance Rat
- Summary -

Observation Type: All Types Sex: Female From Day 1 (Start Date) to 38 (Start Date)	Group 1: Control	Group 2: 30 µg/ animal BNT162a1	Group 3: 10 µg/ animal BNT162a1	Group 4: 30 µg/ animal BNT162b1	Group 5: 100 µg/ animal BNT162b1	Group 6: 30 µg/ animal BNT162c1	Group 7: 100 µg/ animal BNT162b2
Normal							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	1 - 38	1 - 38	1 - 38	1 - 38	1 - 38	1 - 31	1 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	360	360	360	360	360	255	360
Scheduled Removal (Terminal)							
Number of Animals Affected	15	15	15	15	15	15	15
First to Last seen	17 - 38	17 - 38	17 - 38	17 - 38	17 - 38	10 - 31	17 - 38
% of Affected Animals	100	100	100	100	100	100	100
Number of Times Recorded	15	15	15	15	15	15	15

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
2	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
3	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
4	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
5	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
6	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
7	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
8	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
9	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
10	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
11	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
12	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
13	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
14	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
15	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
1	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
2	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
3	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
4	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
5	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
6	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
7	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
8	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
9	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
10	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
11	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
12	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
13	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
14	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
15	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
31	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
32	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
33	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
34	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
35	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
36	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
37	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
38	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
39	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
40	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
41	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
42	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
43	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
44	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
45	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765922

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
31	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
32	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
33	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
34	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
35	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
36	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
37	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
38	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
39	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
40	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
41	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
42	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765923

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
43	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
44	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
45	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765924

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
61	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
62	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
63	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
64	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
65	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
66	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
67	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
68	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
69	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
70	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
71	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
72	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
73	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
74	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
75	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765926

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
61	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
62	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
63	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
64	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
65	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
66	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
67	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
68	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
69	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
70	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
71	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
72	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765927

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
73	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
74	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
75	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765928

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
91	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
92	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
93	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
94	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
95	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
96	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
97	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
98	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
99	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
100	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
101	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
102	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
103	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
104	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
105	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765930

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
91	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
92	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
93	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
94	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
95	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
96	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
97	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
98	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
99	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
100	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
101	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
102	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765931

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
103	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
104	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
105	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765932

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
121	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
122	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
123	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
124	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
125	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
126	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
127	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
128	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
129	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
130	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
131	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
132	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765933

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
133	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
134	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
135	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765934

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
121	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
122	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
123	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
124	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
125	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
126	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
127	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
128	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
129	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
130	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
131	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
132	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
133	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
134	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
135	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765936

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
151	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
152	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
153	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
154	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
155	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
156	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
157	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
158	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
159	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
160	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
161	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
162	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
163	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
164	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
165	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765938

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
151	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
152	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
153	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
154	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
155	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
156	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
157	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
158	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
159	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
160	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
161	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.				
162	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765939

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
163	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
164	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
165	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765940

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
181	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
182	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
183	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
184	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
185	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
186	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
187	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
188	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
189	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
190	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
191	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
192	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765941

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
193	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
194	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
195	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765942

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
181	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
182	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
183	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
184	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
185	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
186	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
187	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
188	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
189	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
190	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
191	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
192	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765943

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Male	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
193	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
194	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
195	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765944

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
16	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
17	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
18	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
19	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
20	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
21	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
22	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
23	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
24	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
25	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
26	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
27	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
28	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765945

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TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
29	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
30	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765946

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
16	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
17	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
18	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
19	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
20	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
21	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
22	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
23	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
24	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
25	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
26	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
27	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
28	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765947

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 1: Control Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
29	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
30	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765948

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
46	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
47	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
48	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
49	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
50	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
51	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
52	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
53	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
54	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
55	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
56	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
57	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
58	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
59	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
60	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765950

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
46	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
47	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
48	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
49	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
50	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
51	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
52	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
53	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
54	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
55	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
56	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
57	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765951

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 2: 30 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
58	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
59	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
60	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765952

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
76	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
77	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
78	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
79	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
80	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
81	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
82	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
83	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
84	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
85	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
86	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
87	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
88	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
89	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
90	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
76	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
77	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
78	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
79	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
80	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
81	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
82	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
83	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
84	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
85	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
86	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
87	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765955

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 3: 10 µg/ animal BNT162a1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
88	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
89	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
90	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
106	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
107	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
108	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
109	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
110	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
111	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
112	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
113	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
114	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
115	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
116	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
117	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765957

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
118	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
119	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
120	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765958

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
106	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
107	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
108	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
109	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
110	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
111	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
112	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
113	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
114	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
115	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
116	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
117	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765959

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 4: 30 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
118	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
119	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
120	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765960

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
136	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
137	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
138	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
139	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
140	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
141	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
142	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
143	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
144	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
145	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
146	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
147	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765961

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
148	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
149	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
150	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765962

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
136	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
137	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
138	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
139	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
140	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
141	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
142	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
143	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
144	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
145	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
146	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
147	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 5: 100 µg/ animal BNT162b1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
148	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
149	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
150	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765964

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
166	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
167	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
168	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
169	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
170	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
171	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
172	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
173	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
174	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
175	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.	.	.	.	.
176	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
177	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
178	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
179	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
180	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

FDA-CBER-2021-5683-0765966

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
166	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
167	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
168	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
169	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
170	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
171	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
172	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
173	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
174	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
175	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
176	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.				
177	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.				

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765967

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 6: 30 µg/ animal BNT162c1 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38			
178	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
179	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			
180	Normal	N	N	N	N	N	N	N	N	N	N	.	.	.	.	.	.	.			
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	K	.	.	.	.	.	.	.			

N=Normal; K=Scheduled Removal

FDA-CBER-2021-5683-0765968

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
196	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
197	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
198	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
199	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
200	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
201	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
202	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
203	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
204	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
205	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	.	.	.	.
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K	.	.	.	.
206	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
207	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
208	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
209	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
210	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

N=Normal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
196	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
197	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
198	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
199	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
200	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
201	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
202	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
203	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
204	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
205	Normal	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.				
206	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
207	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 2-2 Clinical Signs - Systemic Tolerance Rat
- Individual Data -

Group 7: 100 µg/ animal BNT162b2 Sex: Female	Observation Type: All Types	Day(s) Relative to Start Date																				
		22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38				
208	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
209	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				
210	Normal	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N				
	Scheduled Removal (Terminal)	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	K				

N=Normal; K=Scheduled Removal

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		-7 [a1]	-1 [a]	1 [a]	2 [a]	8 [a]	9 [a]	15 [a]
Group 1:	Mean	-	257.62	263.53	268.90	310.87	319.78	356.29
Control	SD	-	6.64	7.58	6.51	12.03	13.46	12.27
	N	-	15	15	15	15	15	15
		-	-	-	-	-	-	-
Group 2:	Mean	-	257.65	261.61	250.35**	293.50**	277.99**	315.29**
30 µg/	SD	-	6.69	6.31	8.19	8.11	9.29	16.84
animal	N	-	15	15	15	15	15	15
BNT162a1	%Diff	-	0.0	-0.7	-6.9	-5.6	-13.1	-11.5
Group 3:	Mean	258.94n	-	314.03**	303.03**	342.02**	323.25	363.25
10 µg/	SD	24.65	-	21.12	21.80	23.55	23.99	25.67
animal	N	15	-	15	15	15	15	15
BNT162a1	%Diff	-	-	19.2	12.7	10.0	1.1	2.0
Group 4:	Mean	-	257.79	263.16	256.27**	304.49	298.98*	337.96*
30 µg/	SD	-	6.87	5.64	5.36	7.53	8.06	13.00
animal	N	-	15	15	15	15	15	15
BNT162b1	%Diff	-	0.1	-0.1	-4.7	-2.1	-6.5	-5.1

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0765973

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		-7	-1	1	2	8	9	15
Group 5:	Mean	256.81n	-	309.21**	281.83	321.17	298.54**	347.63
100 µg/	SD	17.84	-	19.73	19.55	20.99	24.02	26.28
animal	N	15	-	15	15	15	15	15
BNT162b1	%Diff	-	-	17.3	4.8	3.3	-6.6	-2.4
Group 6:	Mean	258.01n	-	308.23**	293.50**	325.49	305.99	348.50
30 µg/	SD	19.50	-	17.40	18.46	24.01	22.53	26.54
animal	N	15	-	15	15	15	15	5
BNT162c1	%Diff	-	-	17.0	9.1	4.7	-4.3	-2.2
Group 7:	Mean	257.88n	-	305.63**	283.37	317.95	293.24**	341.19
100 µg/	SD	19.55	-	20.51	22.56	20.59	21.98	21.54
animal	N	15	-	15	15	15	15	15
BNT162b2	%Diff	-	-	16.0	5.4	2.3	-8.3	-4.2

Anova & Dunnett: ** = $p \leq 0.01$; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		16 [a]	18 [a1]	22 [a1]	25 [a1]	29 [a1]	30 [a1]	32 [a1]
Group 1:	Mean	361.27	362.44	380.10	385.68	409.78	-	418.86
Control	SD	11.98	13.75	19.57	16.43	15.77	-	12.26
	N	15	5	5	5	5	-	5
		-	-	-	-	-	-	-
Group 2:	Mean	301.04**	319.16*	343.06	360.54	392.18	-	398.86
30 µg/	SD	13.62	14.28	16.70	17.61	15.75	-	18.07
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-16.7	-11.9	-9.7	-6.5	-4.3	-	-4.8
Group 3:	Mean	351.17	368.34	389.26	410.54	422.70	-	426.70
10 µg/	SD	25.67	30.64	27.89	32.77	35.01	-	34.60
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-2.8	1.6	2.4	6.4	3.2	-	1.9
Group 4:	Mean	329.54**	354.12	374.26	389.04	410.94	-	420.22
30 µg/	SD	11.94	16.10	16.54	28.23	33.61	-	42.19
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	-8.8	-2.3	-1.5	0.9	0.3	-	0.3

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date						
		16	18	22	25	29	30	32
Group 5:	Mean	327.82**	351.28	369.70	393.08	407.76	-	414.80
100 µg/	SD	28.27	23.29	24.59	29.03	28.89	-	28.04
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	-9.3	-3.1	-2.7	1.9	-0.5	-	-1.0
Group 6:	Mean	-	366.86	386.92	400.70	403.28	404.96 n	-
30 µg/	SD	-	35.54	36.88	33.35	27.03	30.01	-
animal	N	-	5	5	5	5	5	-
BNT162c1	%Diff	-	1.2	1.8	3.9	-1.6	-	-
Group 7:	Mean	320.31**	339.30	362.72	382.86	397.60	-	405.80
100 µg/	SD	22.86	27.06	24.85	26.36	26.87	-	29.28
animal	N	15	5	5	5	5	-	5
BNT162b2	%Diff	-11.3	-6.4	-4.6	-0.7	-3.0	-	-3.1

Anova & Dunnett: ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date	
		36	37
Group 1: Control	Mean	427.06	430.64
	SD	18.28	17.07
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	413.02	417.74
	SD	21.85	26.88
	N	5	5
	%Diff	-3.3	-3.0
Group 3: 10 µg/ animal BNT162a1	Mean	438.92	441.08
	SD	38.53	36.63
	N	5	5
	%Diff	2.8	2.4
Group 4: 30 µg/ animal BNT162b1	Mean	430.80	432.84
	SD	45.93	42.13
	N	5	5
	%Diff	0.9	0.5

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Male		Day(s) Relative to Start Date	
		36	37
Group 5:	Mean	419.80	421.92
100 µg/	SD	25.11	27.60
animal	N	5	5
BNT162b1	%Diff	-1.7	-2.0
Group 6:	Mean	-	-
30 µg/	SD	-	-
animal	N	-	-
BNT162c1	%Diff	-	-
Group 7:	Mean	411.82	417.40
100 µg/	SD	31.28	28.42
animal	N	5	5
BNT162b2	%Diff	-3.6	-3.1

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		-7 [a1]	-1 [a]	1 [a]	2 [a]	8 [a]	9 [a]	15 [a]
Group 1:	Mean	-	213.78	212.25	215.06	231.69	236.97	249.79
Control	SD	-	9.13	9.41	10.81	12.12	13.24	13.90
	N	-	15	15	15	15	15	15
		-	-	-	-	-	-	-
Group 2:	Mean	-	213.85	209.60	205.43	229.60	221.53*	243.21
30 µg/	SD	-	9.08	11.06	9.87	11.80	11.92	10.42
animal	N	-	15	15	15	15	15	15
BNT162a1	%Diff	-	0.0	-1.3	-4.5	-0.9	-6.5	-2.6
Group 3:	Mean	190.83n	-	215.39	211.83	232.60	224.57	243.57
10 µg/	SD	20.28	-	18.50	17.58	20.46	19.61	22.86
animal	N	15	-	15	15	15	15	15
BNT162a1	%Diff	-	-	1.5	-1.5	0.4	-5.2	-2.5
Group 4:	Mean	-	214.15	213.98	214.20	234.73	234.26	258.37
30 µg/	SD	-	9.03	10.29	10.97	17.14	15.66	17.90
animal	N	-	15	15	15	15	15	15
BNT162b1	%Diff	-	0.2	0.8	-0.4	1.3	-1.1	3.4

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05
[a1] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		-7	-1	1	2	8	9	15
Group 5:	Mean	192.28n	-	214.81	204.95	234.26	222.42*	246.11
100 µg/	SD	18.07	-	17.07	14.94	16.46	17.02	19.58
animal	N	15	-	15	15	15	15	15
BNT162b1	%Diff	-	-	1.2	-4.7	1.1	-6.1	-1.5
Group 6:	Mean	193.47n	-	217.13	209.75	230.53	220.42**	237.84
30 µg/	SD	17.74	-	19.32	19.09	23.60	23.19	32.48
animal	N	15	-	15	15	15	15	5
BNT162c1	%Diff	-	-	2.3	-2.5	-0.5	-7.0	-4.8
Group 7:	Mean	192.57n	-	218.14	205.63	228.15	220.75*	238.23
100 µg/	SD	18.31	-	19.76	18.37	17.99	19.85	20.09
animal	N	15	-	15	15	15	15	15
BNT162b2	%Diff	-	-	2.8	-4.4	-1.5	-6.8	-4.6

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		16 [a]	18 [a1]	22 [a]	25 [a2]	29 [a1]	30 [a1]	32 [a1]
Group 1:	Mean	247.66	267.84	273.16	274.66	283.22	-	288.50
Control	SD	13.00	19.29	16.70	16.68	21.37	-	25.05
	N	15	5	5	5	5	-	5
		-	-	-	-	-	-	-
Group 2:	Mean	230.25**	249.48	255.86	263.70	274.06	-	278.90
30 µg/	SD	10.43	14.24	13.76	16.64	7.60	-	15.05
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-7.0	-6.9	-6.3	-4.0	-3.2	-	-3.3
Group 3:	Mean	238.89	251.48	254.12	259.62	272.38	-	272.52
10 µg/	SD	21.23	26.31	18.83	21.02	24.61	-	18.12
animal	N	15	5	5	5	5	-	5
BNT162a1	%Diff	-3.5	-6.1	-7.0	-5.5	-3.8	-	-5.5
Group 4:	Mean	250.33	266.42	270.98	272.64	285.28	-	287.32
30 µg/	SD	17.86	5.68	8.29	8.67	10.15	-	13.05
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	1.1	-0.5	-0.8	-0.7	0.7	-	-0.4

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Log)

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date						
		16	18	22	25	29	30	32
Group 5:	Mean	236.60	248.36	259.16	274.44	276.78	-	274.96
100 µg/	SD	17.79	17.83	21.76	23.21	21.16	-	17.93
animal	N	15	5	5	5	5	-	5
BNT162b1	%Diff	-4.5	-7.3	-5.1	-0.1	-2.3	-	-4.7
Group 6:	Mean	-	248.94	256.08	262.30	274.14	268.30 n	-
30 µg/	SD	-	30.16	33.99	32.06	32.12	32.09	-
animal	N	-	5	5	5	5	5	-
BNT162c1	%Diff	-	-7.1	-6.3	-4.5	-3.2	-	-
Group 7:	Mean	231.70**	238.60	245.28	254.14	264.86	-	268.56
100 µg/	SD	19.18	13.08	18.43	18.64	19.30	-	19.05
animal	N	15	5	5	5	5	-	5
BNT162b2	%Diff	-6.4	-10.9	-10.2	-7.5	-6.5	-	-6.9

Anova & Dunnett: ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date	
		36	37
Group 1: Control	Mean	299.72	296.84
	SD	26.90	29.87
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	285.70	288.34
	SD	16.50	19.50
	N	5	5
	%Diff	-4.7	-2.9
Group 3: 10 µg/ animal BNT162a1	Mean	275.70	277.00
	SD	20.21	21.68
	N	5	5
	%Diff	-8.0	-6.7
Group 4: 30 µg/ animal BNT162b1	Mean	294.12	289.40
	SD	10.23	12.11
	N	5	5
	%Diff	-1.9	-2.5

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Body Weight (g)

Sex: Female		Day(s) Relative to Start Date	
		36	37
Group 5:	Mean	283.10	283.22
100 µg/	SD	16.64	18.17
animal	N	5	5
BNT162b1	%Diff	-5.5	-4.6
Group 6:	Mean	-	-
30 µg/	SD	-	-
animal	N	-	-
BNT162c1	%Diff	-	-
Group 7:	Mean	274.54	266.64
100 µg/	SD	19.52	21.63
animal	N	5	5
BNT162b2	%Diff	-8.4	-10.2

Anova & Dunnett

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TABLE 3-1 Body Weight - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Weight	2	Male	2	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	8	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	9	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	15	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	3	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	3	Male	1	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	3	Male	2	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	3	Male	8	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	4	Male	2	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	4	Male	9	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Weight	4	Male	15	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Weight	2	Male	16	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	2	Male	18	*	Anova & Dunnett: * = p ≤ 0.05
	Body Weight	4	Male	16	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	5	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	5	Male	1	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	5	Male	9	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	6	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	6	Male	1	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	6	Male	2	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	7	Male	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Male	1	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	7	Male	9	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	5	Male	16	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	6	Male	30	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Male	16	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 3-1 Body Weight - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Weight	2	Female	9	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Weight	3	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	2	Female	16	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Weight	5	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	5	Female	9	*	Anova & Dunnett: * = p ≤ 0.05
	Body Weight	6	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	6	Female	9	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Weight	7	Female	-7	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Female	9	*	Anova & Dunnett: * = p ≤ 0.05
	Body Weight	6	Female	30	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Weight	7	Female	16	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
1	-	251.8	258.8	263.2	303.8	313.1	350.3
2	-	255.5	259.7	261.3	303.8	307.1	340.3
3	-	256.1	262.9	271.5	322.0	329.2	371.3
4	-	261.1	266.1	275.6	316.1	323.3	358.0
5	-	253.1	262.7	268.2	314.1	318.6	346.0
6	-	257.7	264.3	272.2	314.7	322.4	373.9
7	-	250.8	258.6	266.8	308.0	319.4	351.8
8	-	266.4	273.3	275.7	318.5	329.4	360.0
9	-	250.2	255.1	262.8	317.2	327.9	373.7
10	-	268.4	274.2	277.0	328.5	341.0	366.7
11	-	267.7	270.9	276.9	316.6	325.9	355.0
12	-	249.1	254.8	261.4	279.1	286.3	341.9
13	-	264.4	278.4	275.4	317.4	330.6	363.0
14	-	252.5	254.9	257.8	295.4	301.5	334.6
15	-	259.5	258.3	267.7	307.8	321.0	357.8
Mean	-	257.62	263.53	268.90	310.87	319.78	356.29
SD	-	6.64	7.58	6.51	12.03	13.46	12.27
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
1	351.1	-	-	-	-	-	-
2	345.4	-	-	-	-	-	-
3	376.9	-	-	-	-	-	-
4	361.8	-	-	-	-	-	-
5	351.3	-	-	-	-	-	-
6	377.6	-	-	-	-	-	-
7	355.6	-	-	-	-	-	-
8	365.0	-	-	-	-	-	-
9	375.6	-	-	-	-	-	-
10	369.6	-	-	-	-	-	-
11	364.2	365.0	377.9	385.3	412.9	416.5	419.9
12	352.6	351.8	373.8	371.2	397.0	414.3	424.7
13	365.6	375.5	396.4	404.0	425.8	431.8	443.4
14	337.6	344.9	351.8	367.7	390.1	401.9	401.4
15	369.1	375.0	400.6	400.2	423.1	429.8	445.9
Mean	361.27	362.44	380.10	385.68	409.78	418.86	427.06
SD	11.98	13.75	19.57	16.43	15.77	12.26	18.28
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date
	37
1	-
2	-
3	-
4	-
5	-
6	-
7	-
8	-
9	-
10	-
11	425.1
12	431.7
13	443.1
14	404.9
15	448.4
Mean	430.64
SD	17.07
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
31	-	265.3	270.3	257.9	285.4	268.0	310.1
32	-	253.3	258.0	231.7	292.3	271.2	303.0
33	-	257.9	256.1	253.0	305.1	289.7	347.2
34	-	267.6	272.2	258.8	301.9	284.1	315.0
35	-	256.2	263.5	251.9	295.0	281.3	321.2
36	-	249.9	253.9	242.5	289.2	278.6	309.8
37	-	268.5	267.1	253.3	293.2	279.6	316.5
38	-	265.7	269.6	262.1	309.9	284.7	326.8
39	-	249.2	259.9	239.5	279.8	257.3	269.7
40	-	260.7	266.7	257.3	291.2	276.2	307.7
41	-	255.8	258.5	250.3	291.8	286.3	316.7
42	-	260.1	260.2	252.7	288.1	273.5	309.5
43	-	252.6	260.8	254.3	298.0	292.1	330.8
44	-	250.7	252.8	245.2	283.8	267.7	317.4
45	-	251.2	254.5	244.7	297.8	279.5	327.9
Mean	-	257.65	261.61	250.35	293.50	277.99	315.29
SD	-	6.69	6.31	8.19	8.11	9.29	16.84
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
31	291.4	-	-	-	-	-	-
32	293.6	-	-	-	-	-	-
33	319.2	-	-	-	-	-	-
34	303.9	-	-	-	-	-	-
35	306.5	-	-	-	-	-	-
36	300.7	-	-	-	-	-	-
37	305.1	-	-	-	-	-	-
38	313.2	-	-	-	-	-	-
39	260.9	-	-	-	-	-	-
40	293.9	-	-	-	-	-	-
41	304.0	312.3	329.6	343.6	377.1	382.2	392.3
42	297.5	309.0	331.4	347.5	379.0	380.9	398.7
43	315.1	344.3	370.3	388.5	415.6	424.7	448.1
44	304.9	315.1	336.8	361.5	390.7	403.4	408.3
45	305.7	315.1	347.2	361.6	398.5	403.1	417.7
Mean	301.04	319.16	343.06	360.54	392.18	398.86	413.02
SD	13.62	14.28	16.70	17.61	15.75	18.07	21.85
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
31	-
32	-
33	-
34	-
35	-
36	-
37	-
38	-
39	-
40	-
41	393.2
42	399.6
43	461.4
44	412.1
45	422.4
Mean	417.74
SD	26.88
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
61	286.5	-	341.7	327.9	365.9	353.3	395.8
62	222.3	-	290.4	273.7	315.6	289.4	331.6
63	287.6	-	335.3	339.7	365.9	352.1	388.5
64	272.1	-	316.1	303.4	336.8	317.0	352.4
65	229.0	-	293.2	285.3	332.7	316.1	361.4
66	296.9	-	338.8	320.6	344.0	331.6	367.0
67	278.5	-	335.8	324.9	375.7	351.3	394.9
68	231.8	-	285.5	266.6	304.4	280.0	314.8
69	234.6	-	295.0	286.4	315.4	302.6	345.1
70	269.0	-	332.3	322.1	369.0	344.2	381.6
71	246.4	-	300.4	292.8	339.3	321.4	363.1
72	238.8	-	296.1	288.6	322.4	311.7	349.8
73	243.0	-	292.2	287.6	318.1	297.2	330.8
74	274.4	-	331.1	315.9	360.2	333.9	378.6
75	273.2	-	326.5	309.9	364.9	347.0	393.3
Mean	258.94	-	314.03	303.03	342.02	323.25	363.25
SD	24.65	-	21.12	21.80	23.55	23.99	25.67
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
61	377.1	-	-	-	-	-	-
62	325.2	-	-	-	-	-	-
63	374.3	-	-	-	-	-	-
64	348.8	-	-	-	-	-	-
65	355.0	-	-	-	-	-	-
66	347.0	-	-	-	-	-	-
67	382.7	-	-	-	-	-	-
68	296.6	-	-	-	-	-	-
69	335.0	-	-	-	-	-	-
70	369.8	-	-	-	-	-	-
71	342.9	356.1	380.7	399.9	416.1	423.9	445.2
72	338.0	347.0	373.3	385.5	395.4	394.9	406.6
73	319.4	337.5	356.2	378.4	385.0	391.7	393.4
74	372.7	392.7	414.0	433.9	450.5	453.7	464.2
75	383.0	408.4	422.1	455.0	466.5	469.3	485.2
Mean	351.17	368.34	389.26	410.54	422.70	426.70	438.92
SD	25.67	30.64	27.89	32.77	35.01	34.60	38.53
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
61	-
62	-
63	-
64	-
65	-
66	-
67	-
68	-
69	-
70	-
71	447.4
72	406.5
73	400.7
74	466.9
75	483.9
Mean	441.08
SD	36.63
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
91	-	255.7	258.5	255.6	301.2	300.0	334.8
92	-	250.0	257.6	250.4	300.2	293.9	321.0
93	-	249.3	259.3	254.0	306.4	298.2	335.4
94	-	250.2	257.8	253.6	290.9	286.3	316.8
95	-	255.0	263.7	252.3	298.1	299.8	335.7
96	-	267.5	272.8	263.4	317.5	311.9	365.4
97	-	259.5	261.0	253.5	300.1	290.6	336.6
98	-	250.8	254.9	252.0	295.7	293.0	328.0
99	-	267.8	268.3	264.3	312.4	309.1	351.1
100	-	268.9	271.6	261.4	307.7	293.0	332.1
101	-	264.1	269.1	260.2	306.7	302.5	326.7
102	-	252.4	258.3	247.0	298.1	290.1	341.4
103	-	257.5	263.0	260.1	313.6	313.3	356.2
104	-	261.9	268.3	263.1	312.5	301.0	344.4
105	-	256.3	263.2	253.2	306.2	302.0	343.8
Mean	-	257.79	263.16	256.27	304.49	298.98	337.96
SD	-	6.87	5.64	5.36	7.53	8.06	13.00
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
91	329.1	-	-	-	-	-	-
92	315.9	-	-	-	-	-	-
93	323.2	-	-	-	-	-	-
94	319.3	-	-	-	-	-	-
95	326.7	-	-	-	-	-	-
96	352.5	-	-	-	-	-	-
97	324.5	-	-	-	-	-	-
98	322.1	-	-	-	-	-	-
99	342.5	-	-	-	-	-	-
100	318.1	-	-	-	-	-	-
101	321.5	332.2	358.3	356.4	372.2	367.6	383.9
102	331.1	353.2	362.2	380.7	394.9	402.9	398.3
103	355.5	377.3	400.3	433.8	460.7	482.0	500.5
104	332.5	357.0	372.6	382.5	401.8	414.3	423.9
105	328.6	350.9	377.9	391.8	425.1	434.3	447.4
Mean	329.54	354.12	374.26	389.04	410.94	420.22	430.80
SD	11.94	16.10	16.54	28.23	33.61	42.19	45.93
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
91	-
92	-
93	-
94	-
95	-
96	-
97	-
98	-
99	-
100	-
101	391.9
102	403.8
103	500.3
104	430.5
105	437.7
Mean	432.84
SD	42.13
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
121	275.7	-	333.6	301.4	338.0	319.2	371.4
122	243.8	-	292.5	261.7	294.8	271.8	311.6
123	236.5	-	292.5	268.3	314.2	299.2	345.9
124	274.7	-	332.5	320.5	361.3	349.7	401.8
125	239.3	-	293.2	272.2	298.2	281.4	323.1
126	273.4	-	326.7	297.6	336.7	321.4	374.8
127	241.4	-	292.9	261.3	308.9	284.6	335.2
128	239.9	-	287.7	256.4	301.4	271.8	322.6
129	269.8	-	313.6	285.6	325.7	301.5	340.2
130	238.0	-	290.8	265.7	310.1	283.9	343.8
131	281.9	-	343.9	306.3	350.7	326.5	380.4
132	248.1	-	297.0	275.0	309.0	280.0	331.6
133	241.6	-	292.6	267.3	297.5	270.2	317.3
134	278.5	-	327.4	298.9	342.0	319.5	368.2
135	269.6	-	321.3	289.2	329.0	297.4	346.5
Mean	256.81	-	309.21	281.83	321.17	298.54	347.63
SD	17.84	-	19.73	19.55	20.99	24.02	26.28
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
121	359.4	-	-	-	-	-	-
122	296.4	-	-	-	-	-	-
123	328.9	-	-	-	-	-	-
124	387.5	-	-	-	-	-	-
125	310.9	-	-	-	-	-	-
126	359.7	-	-	-	-	-	-
127	314.8	-	-	-	-	-	-
128	291.3	-	-	-	-	-	-
129	319.8	-	-	-	-	-	-
130	318.3	-	-	-	-	-	-
131	354.9	381.6	402.1	435.6	445.7	458.3	452.3
132	305.3	332.5	348.1	375.2	378.8	403.6	409.1
133	294.9	326.3	344.3	362.4	380.3	385.1	392.4
134	346.6	367.6	385.7	408.0	425.2	424.5	439.7
135	328.6	348.4	368.3	384.2	408.8	402.5	405.5
Mean	327.82	351.28	369.70	393.08	407.76	414.80	419.80
SD	28.27	23.29	24.59	29.03	28.89	28.04	25.11
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
121	-
122	-
123	-
124	-
125	-
126	-
127	-
128	-
129	-
130	-
131	461.8
132	407.9
133	391.7
134	437.1
135	411.1
Mean	421.92
SD	27.60
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	-7	1	2	8	9	15	18
151	244.4	291.9	280.0	305.1	285.3	-	-
152	294.0	337.0	319.8	347.9	329.4	-	-
153	239.2	290.7	272.2	292.7	280.1	-	-
154	238.9	298.0	293.1	327.1	308.0	-	-
155	247.2	310.0	295.4	329.5	316.4	-	-
156	247.7	300.5	292.7	318.5	297.2	-	-
157	275.5	326.4	310.7	348.9	330.5	-	-
158	244.5	292.2	269.5	287.6	272.4	-	-
159	242.5	296.7	292.4	321.5	312.9	-	-
160	242.4	286.1	264.9	299.7	274.6	-	-
161	285.9	337.3	322.4	356.2	331.0	367.7	396.5
162	242.8	296.1	275.9	306.6	286.1	312.5	318.0
163	277.5	324.3	308.9	355.6	336.0	369.9	394.3
164	269.6	315.8	292.0	326.2	300.4	327.7	340.4
165	278.1	320.5	312.6	359.2	329.6	364.7	385.1
Mean	258.01	308.23	293.50	325.49	305.99	348.50	366.86
SD	19.50	17.40	18.46	24.01	22.53	26.54	35.54
N	15	15	15	15	15	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	22	25	29	30
151	-	-	-	-
152	-	-	-	-
153	-	-	-	-
154	-	-	-	-
155	-	-	-	-
156	-	-	-	-
157	-	-	-	-
158	-	-	-	-
159	-	-	-	-
160	-	-	-	-
161	408.2	410.5	407.4	413.9
162	335.3	356.1	367.7	361.7
163	412.6	425.8	424.8	429.3
164	360.5	376.5	384.5	387.5
165	418.0	434.6	432.0	432.4
Mean	386.92	400.70	403.28	404.96
SD	36.88	33.35	27.03	30.01
N	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
181	283.0	-	338.3	327.4	355.2	332.4	371.5
182	245.6	-	291.8	262.7	299.9	273.2	318.0
183	244.2	-	301.1	270.6	320.6	293.3	342.7
184	236.4	-	288.7	264.9	305.9	283.2	329.4
185	281.3	-	336.7	307.0	347.7	314.0	375.5
186	242.7	-	275.7	253.9	291.6	257.4	307.3
187	277.3	-	324.9	296.5	334.2	298.7	346.2
188	241.5	-	291.4	270.2	307.1	284.6	342.6
189	247.9	-	297.8	271.8	304.8	275.6	327.6
190	241.6	-	291.1	267.3	308.9	290.6	339.2
191	247.5	-	293.4	276.0	303.5	280.1	327.8
192	284.5	-	325.2	305.0	334.6	317.3	361.7
193	282.3	-	326.2	313.3	341.0	322.4	365.4
194	237.3	-	283.5	263.7	289.8	266.3	309.3
195	275.1	-	318.6	300.3	324.5	309.5	353.6
Mean	257.88	-	305.63	283.37	317.95	293.24	341.19
SD	19.55	-	20.51	22.56	20.59	21.98	21.54
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
181	353.6	-	-	-	-	-	-
182	294.8	-	-	-	-	-	-
183	320.2	-	-	-	-	-	-
184	307.8	-	-	-	-	-	-
185	348.7	-	-	-	-	-	-
186	290.5	-	-	-	-	-	-
187	318.9	-	-	-	-	-	-
188	316.9	-	-	-	-	-	-
189	308.8	-	-	-	-	-	-
190	322.2	-	-	-	-	-	-
191	307.9	314.8	339.3	362.8	376.8	387.6	392.3
192	345.9	356.7	379.1	398.4	407.4	419.4	430.0
193	354.6	366.3	385.1	411.8	425.3	435.7	440.6
194	282.3	305.9	332.3	348.3	362.3	364.0	366.5
195	331.5	352.8	377.8	393.0	416.2	422.3	429.7
Mean	320.31	339.30	362.72	382.86	397.60	405.80	411.82
SD	22.86	27.06	24.85	26.36	26.87	29.28	31.28
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Male Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date
	37
181	-
182	-
183	-
184	-
185	-
186	-
187	-
188	-
189	-
190	-
191	403.6
192	427.4
193	444.9
194	374.7
195	436.4
Mean	417.40
SD	28.42
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
16	-	226.6	219.9	230.2	249.9	246.3	268.1
17	-	204.0	199.0	206.0	235.3	246.8	243.4
18	-	200.6	199.3	204.0	211.8	220.4	235.4
19	-	205.9	206.3	207.3	220.9	223.7	243.3
20	-	220.0	215.5	214.7	230.5	229.6	245.8
21	-	207.2	203.0	204.5	229.6	226.6	235.7
22	-	202.2	203.8	205.6	217.9	226.3	232.7
23	-	209.0	205.9	208.8	221.8	227.8	242.1
24	-	210.3	212.6	217.6	231.9	237.2	252.3
25	-	219.3	213.9	217.3	238.0	238.9	248.5
26	-	219.7	217.8	215.8	225.7	226.6	241.4
27	-	226.2	231.2	239.7	249.8	266.5	279.8
28	-	227.8	224.5	226.0	253.8	258.4	268.2
29	-	212.5	211.7	205.2	229.8	239.0	246.7
30	-	215.4	219.4	223.2	228.7	240.5	263.4
Mean	-	213.78	212.25	215.06	231.69	236.97	249.79
SD	-	9.13	9.41	10.81	12.12	13.24	13.90
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
16	269.6	-	-	-	-	-	-
17	242.1	-	-	-	-	-	-
18	235.8	-	-	-	-	-	-
19	236.9	-	-	-	-	-	-
20	246.6	-	-	-	-	-	-
21	238.7	-	-	-	-	-	-
22	231.1	-	-	-	-	-	-
23	242.4	-	-	-	-	-	-
24	255.8	-	-	-	-	-	-
25	250.6	-	-	-	-	-	-
26	238.7	242.7	260.6	252.0	256.7	253.0	270.6
27	264.6	293.9	298.1	295.9	310.7	312.0	320.7
28	273.8	272.6	281.4	285.0	297.4	312.3	332.6
29	238.5	256.7	257.6	269.4	270.5	277.1	276.9
30	249.7	273.3	268.1	271.0	280.8	288.1	297.8
Mean	247.66	267.84	273.16	274.66	283.22	288.50	299.72
SD	13.00	19.29	16.70	16.68	21.37	25.05	26.90
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 1: Control	Day(s) Relative to Start Date
	37
16	-
17	-
18	-
19	-
20	-
21	-
22	-
23	-
24	-
25	-
26	262.9
27	321.3
28	334.5
29	281.5
30	284.0
Mean	296.84
SD	29.87
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
46	-	226.6	224.6	217.0	241.8	235.0	245.7
47	-	216.7	215.5	205.2	235.7	231.3	239.6
48	-	208.1	205.0	203.7	228.9	228.3	258.4
49	-	219.5	210.7	206.9	227.5	211.0	241.7
50	-	216.0	215.5	206.9	220.4	224.1	243.8
51	-	208.9	200.8	193.6	228.6	203.6	227.9
52	-	200.6	194.0	193.9	218.5	218.6	255.4
53	-	204.0	192.6	194.1	220.9	212.8	237.3
54	-	213.0	213.4	204.3	229.8	218.7	233.0
55	-	202.5	203.5	195.9	225.3	211.6	231.6
56	-	204.7	193.0	195.0	216.6	212.7	235.7
57	-	212.3	211.5	207.5	232.1	227.6	248.8
58	-	225.5	224.6	224.8	242.6	231.4	253.7
59	-	228.6	215.9	217.6	259.8	247.3	261.4
60	-	220.8	223.4	215.1	215.5	208.9	234.1
Mean	-	213.85	209.60	205.43	229.60	221.53	243.21
SD	-	9.08	11.06	9.87	11.80	11.92	10.42
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
46	233.6	-	-	-	-	-	-
47	233.4	-	-	-	-	-	-
48	253.4	-	-	-	-	-	-
49	224.8	-	-	-	-	-	-
50	234.5	-	-	-	-	-	-
51	212.2	-	-	-	-	-	-
52	232.1	-	-	-	-	-	-
53	217.0	-	-	-	-	-	-
54	223.7	-	-	-	-	-	-
55	223.1	-	-	-	-	-	-
56	222.5	232.8	236.6	253.6	277.0	284.4	276.8
57	234.3	256.2	258.8	261.0	269.7	266.9	271.8
58	237.7	258.5	271.8	287.2	278.4	291.6	302.9
59	243.7	264.2	263.9	272.3	282.1	292.4	304.4
60	227.8	235.7	248.2	244.4	263.1	259.2	272.6
Mean	230.25	249.48	255.86	263.70	274.06	278.90	285.70
SD	10.43	14.24	13.76	16.64	7.60	15.05	16.50
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
46	-
47	-
48	-
49	-
50	-
51	-
52	-
53	-
54	-
55	-
56	280.6
57	270.1
58	314.9
59	302.6
60	273.5
Mean	288.34
SD	19.50
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
76	182.3	-	205.4	194.0	226.0	212.1	245.1
77	194.8	-	225.0	219.6	238.5	229.4	242.5
78	176.3	-	202.6	195.0	220.1	214.5	232.7
79	168.7	-	247.4	242.7	264.6	257.9	284.8
80	168.7	-	193.5	188.7	199.8	197.6	206.5
81	180.6	-	204.9	207.7	243.9	231.2	229.2
82	238.1	-	249.8	240.3	279.4	268.1	279.1
83	195.6	-	206.1	208.1	228.8	217.1	231.3
84	184.8	-	201.0	202.2	219.6	210.8	235.6
85	191.5	-	208.5	213.4	227.7	214.9	236.2
86	192.5	-	215.4	206.7	221.8	218.6	225.8
87	183.2	-	211.3	205.0	228.6	219.1	274.1
88	231.8	-	245.5	240.2	252.5	249.0	269.7
89	199.2	-	218.1	219.4	225.7	221.3	237.7
90	174.4	-	196.3	194.4	212.0	206.9	223.2
Mean	190.83	-	215.39	211.83	232.60	224.57	243.57
SD	20.28	-	18.50	17.58	20.46	19.61	22.86
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
76	238.3	-	-	-	-	-	-
77	233.1	-	-	-	-	-	-
78	220.6	-	-	-	-	-	-
79	279.3	-	-	-	-	-	-
80	210.1	-	-	-	-	-	-
81	234.9	-	-	-	-	-	-
82	278.9	-	-	-	-	-	-
83	228.7	-	-	-	-	-	-
84	231.4	-	-	-	-	-	-
85	231.1	-	-	-	-	-	-
86	222.0	235.8	238.3	244.2	252.5	253.4	259.7
87	257.5	287.5	268.8	275.4	285.9	293.2	287.0
88	263.3	267.6	278.6	286.9	304.5	288.3	305.0
89	235.3	245.5	248.8	254.6	275.0	271.6	270.1
90	218.8	221.0	236.1	237.0	244.0	256.1	256.7
Mean	238.89	251.48	254.12	259.62	272.38	272.52	275.70
SD	21.23	26.31	18.83	21.02	24.61	18.12	20.21
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date
	37
76	-
77	-
78	-
79	-
80	-
81	-
82	-
83	-
84	-
85	-
86	260.6
87	292.5
88	306.2
89	270.5
90	255.2
Mean	277.00
SD	21.68
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
106	-	203.8	203.8	201.3	224.4	220.7	262.9
107	-	225.3	225.6	226.0	246.9	241.9	252.9
108	-	207.8	201.4	198.8	232.1	227.7	242.0
109	-	223.3	219.9	222.4	260.5	266.6	299.4
110	-	218.0	215.6	215.8	214.8	224.3	249.5
111	-	227.7	228.5	234.4	252.8	255.4	267.5
112	-	203.8	198.7	194.8	197.6	217.5	227.3
113	-	215.2	221.1	218.8	256.8	252.1	283.4
114	-	200.3	202.4	203.5	222.9	219.2	247.3
115	-	205.8	200.0	207.6	225.7	216.8	240.6
116	-	209.8	215.8	220.4	230.5	234.8	265.7
117	-	215.0	215.7	214.2	230.8	224.7	250.1
118	-	210.2	213.0	215.0	252.7	251.3	271.3
119	-	226.4	226.6	218.8	233.4	227.9	257.1
120	-	219.8	221.6	221.2	239.1	233.0	258.5
Mean	-	214.15	213.98	214.20	234.73	234.26	258.37
SD	-	9.03	10.29	10.97	17.14	15.66	17.90
N	-	15	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
106	254.3	-	-	-	-	-	-
107	248.6	-	-	-	-	-	-
108	236.8	-	-	-	-	-	-
109	296.8	-	-	-	-	-	-
110	250.0	-	-	-	-	-	-
111	265.8	-	-	-	-	-	-
112	226.0	-	-	-	-	-	-
113	271.6	-	-	-	-	-	-
114	231.5	-	-	-	-	-	-
115	240.6	-	-	-	-	-	-
116	246.1	273.3	275.2	270.5	281.2	289.6	293.8
117	243.5	261.6	268.5	260.1	274.0	274.7	283.9
118	261.6	262.9	277.0	284.2	300.6	308.0	309.7
119	241.6	271.9	276.7	274.4	289.4	286.4	297.0
120	240.2	262.4	257.5	274.0	281.2	277.9	286.2
Mean	250.33	266.42	270.98	272.64	285.28	287.32	294.12
SD	17.86	5.68	8.29	8.67	10.15	13.05	10.23
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
106	-
107	-
108	-
109	-
110	-
111	-
112	-
113	-
114	-
115	-
116	291.7
117	283.0
118	307.0
119	291.0
120	274.3
Mean	289.40
SD	12.11
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
136	191.5	-	218.3	210.2	240.9	231.4	271.9
137	192.7	-	206.1	195.5	233.8	218.7	240.4
138	194.9	-	204.1	201.7	214.0	208.4	225.0
139	183.5	-	214.7	203.8	230.5	226.7	238.3
140	182.0	-	196.2	192.2	216.2	204.9	222.1
141	233.9	-	249.4	234.2	264.7	254.9	263.7
142	182.2	-	203.6	194.6	227.5	210.2	234.1
143	175.9	-	207.7	199.9	225.1	218.9	257.7
144	183.3	-	214.1	197.4	247.6	230.5	277.5
145	229.5	-	248.3	236.9	269.0	254.7	270.3
146	174.2	-	189.5	185.0	215.5	194.8	212.0
147	198.2	-	219.4	205.1	226.4	217.0	237.2
148	172.0	-	202.2	190.6	224.9	208.5	245.0
149	191.8	-	220.1	211.0	241.2	233.7	257.6
150	198.6	-	228.4	216.2	236.6	223.0	238.8
Mean	192.28	-	214.81	204.95	234.26	222.42	246.11
SD	18.07	-	17.07	14.94	16.46	17.02	19.58
N	15	-	15	15	15	15	15

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
136	262.1	-	-	-	-	-	-
137	227.5	-	-	-	-	-	-
138	216.9	-	-	-	-	-	-
139	243.1	-	-	-	-	-	-
140	220.4	-	-	-	-	-	-
141	248.3	-	-	-	-	-	-
142	224.7	-	-	-	-	-	-
143	251.9	-	-	-	-	-	-
144	253.5	-	-	-	-	-	-
145	263.3	-	-	-	-	-	-
146	203.0	234.3	257.5	275.8	259.8	260.7	262.0
147	231.8	242.9	249.4	255.2	266.5	261.5	276.8
148	223.8	232.3	240.9	261.2	265.3	269.2	280.1
149	248.4	274.9	296.6	313.7	312.2	304.1	307.0
150	230.3	257.4	251.4	266.3	280.1	279.3	289.6
Mean	236.60	248.36	259.16	274.44	276.78	274.96	283.10
SD	17.79	17.83	21.76	23.21	21.16	17.93	16.64
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date
	37
136	-
137	-
138	-
139	-
140	-
141	-
142	-
143	-
144	-
145	-
146	261.3
147	276.6
148	275.8
149	308.1
150	294.3
Mean	283.22
SD	18.17
N	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	-7	1	2	8	9	15	18
166	193.9	207.4	212.1	227.3	219.8	-	-
167	186.6	219.3	206.4	233.9	224.7	-	-
168	172.2	201.4	184.5	199.8	196.7	-	-
169	197.5	209.9	212.1	240.6	226.4	-	-
170	231.7	252.7	245.3	260.8	255.6	-	-
171	199.4	204.3	213.0	199.9	217.1	-	-
172	197.5	214.4	209.8	227.7	208.9	-	-
173	191.0	230.1	213.3	229.0	209.1	-	-
174	185.0	215.6	202.4	222.5	213.0	-	-
175	181.6	216.2	203.2	236.8	221.7	-	-
176	194.7	197.4	195.2	216.6	200.2	214.6	225.3
177	186.6	206.4	209.8	223.3	213.2	238.9	269.3
178	180.5	206.0	193.5	223.0	209.1	217.0	221.7
179	171.9	208.5	189.4	220.3	203.5	225.3	237.2
180	231.9	267.3	256.3	296.5	287.3	293.4	291.2
Mean	193.47	217.13	209.75	230.53	220.42	237.84	248.94
SD	17.74	19.32	19.09	23.60	23.19	32.48	30.16
N	15	15	15	15	15	5	5

(b) (4)

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	22	25	29	30
166	-	-	-	-
167	-	-	-	-
168	-	-	-	-
169	-	-	-	-
170	-	-	-	-
171	-	-	-	-
172	-	-	-	-
173	-	-	-	-
174	-	-	-	-
175	-	-	-	-
176	234.1	247.4	255.9	251.5
177	253.2	263.1	265.9	265.7
178	235.8	236.6	253.6	242.0
179	241.9	247.3	264.5	258.8
180	315.4	317.1	330.8	323.5
Mean	256.08	262.30	274.14	268.30
SD	33.99	32.06	32.12	32.09
N	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	-7	-1	1	2	8	9	15
196	230.6	-	241.3	232.0	247.8	246.3	271.6
197	182.6	-	199.0	195.1	219.5	207.3	210.8
198	171.6	-	196.5	187.2	217.2	207.6	223.7
199	182.0	-	204.8	180.1	211.1	197.1	228.9
200	235.1	-	264.2	245.2	266.6	259.2	274.7
201	188.8	-	214.8	198.7	229.5	220.8	248.2
202	186.3	-	208.0	196.6	221.7	209.4	213.0
203	198.3	-	227.5	209.9	235.0	228.9	245.4
204	199.6	-	237.1	228.5	251.0	253.4	248.1
205	196.3	-	227.6	212.7	234.7	228.3	245.2
206	179.0	-	208.4	194.5	213.0	203.4	232.0
207	193.8	-	215.6	202.9	219.1	212.6	233.8
208	174.6	-	188.3	185.7	195.1	194.3	211.7
209	182.6	-	210.9	200.5	223.0	214.7	228.9
210	187.3	-	228.1	214.9	237.9	227.9	257.5
Mean	192.57	-	218.14	205.63	228.15	220.75	238.23
SD	18.31	-	19.76	18.37	17.99	19.85	20.09
N	15	-	15	15	15	15	15

(b) (4)

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	16	18	22	25	29	32	36
196	270.2	-	-	-	-	-	-
197	215.4	-	-	-	-	-	-
198	215.2	-	-	-	-	-	-
199	210.2	-	-	-	-	-	-
200	265.5	-	-	-	-	-	-
201	227.1	-	-	-	-	-	-
202	215.1	-	-	-	-	-	-
203	238.2	-	-	-	-	-	-
204	256.7	-	-	-	-	-	-
205	231.4	-	-	-	-	-	-
206	217.7	231.3	236.5	246.3	255.8	262.7	263.5
207	230.8	245.3	247.7	256.7	268.8	271.9	277.7
208	216.2	221.3	220.4	229.3	238.6	240.8	248.9
209	225.1	239.6	251.7	258.0	270.3	274.3	282.0
210	240.7	255.5	270.1	280.4	290.8	293.1	300.6
Mean	231.70	238.60	245.28	254.14	264.86	268.56	274.54
SD	19.18	13.08	18.43	18.64	19.30	19.05	19.52
N	15	5	5	5	5	5	5

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TABLE 3-2 Body Weight - Individual Data Rat

Sex: Female Body Weight (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date
	37
196	-
197	-
198	-
199	-
200	-
201	-
202	-
203	-
204	-
205	-
206	253.5
207	273.8
208	238.8
209	271.3
210	295.8
Mean	266.64
SD	21.63
N	5

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 1: Control	Mean	2.06	17.97	21.34	35.25	37.14	1.29	6.19
	SD	1.33	3.46	3.76	4.75	4.80	1.26	2.26
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	-4.30	12.23	6.31	20.60	15.14	4.46	12.27
	SD	2.23	3.49	4.18	7.32	6.02	2.72	3.47
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	-3.51	8.94	2.93	15.71	11.87	4.84	10.86
	SD	1.94	3.06	3.14	4.06	4.61	1.57	0.53
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	-2.61	15.71	13.63	28.43	25.24	6.06	12.10
	SD	1.19	1.83	2.60	4.14	4.20	1.59	2.03
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	-8.87	3.88	-3.50	12.41	5.95	7.83	13.49
	SD	1.89	2.37	3.52	4.18	4.68	1.97	2.11
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
Group 6:	Mean	-4.79	5.54	-0.77	10.03	15.69	22.03	26.48
30 µg/	SD	2.10	3.57	3.63	0.87	3.43	3.63	3.18
animal	N	15	15	15	5	5	5	5
BNT162c1		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 7:	Mean	-7.34	4.06	-4.07	11.69	4.82	4.69	12.02
100 µg/	SD	2.02	1.61	2.59	2.88	3.41	2.59	3.78
animal	N	15	15	15	15	15	5	5
BNT162b2		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 1: Control	Mean	7.78	14.52	17.09	19.35	20.35
	SD	2.20	1.57	1.80	2.43	2.22
	N	5	5	5	5	5
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	18.00	28.37	30.54	35.16	36.68
	SD	3.69	3.00	3.62	4.80	6.31
	N	5	5	5	5	5
		-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	16.87	20.31	21.47	24.91	25.56
	SD	1.90	1.92	2.68	3.60	3.64
	N	5	5	5	5	5
		-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	16.43	22.97	25.68	28.83	29.45
	SD	4.31	6.22	8.45	9.49	7.98
	N	5	5	5	5	5
		-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	20.63	25.14	27.38	28.95	29.55
	SD	3.04	2.37	4.60	4.47	3.84
	N	5	5	5	5	5
		-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date	
		9 → 29	9 → 30
Group 6:	Mean	27.42	27.88
30 µg/	SD	2.94	2.36
animal	N	5	5
BNT162c1		-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Male		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 7:	Mean	18.21	22.80	25.27	27.09	28.90
100 µg/	SD	3.18	4.24	3.17	2.73	4.10
animal	N	5	5	5	5	5
BNT162b2		-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 1:	Mean	1.32	9.19	11.67	17.66	16.70	5.88	8.00
Control	SD	1.94	3.95	4.48	3.15	3.82	5.01	3.56
	N	15	15	15	15	15	5	5
		-	-	-	-	-	-	-
Group 2:	Mean	-1.94	9.69	5.83	16.29	10.04	6.92	9.68
30 µg/	SD	2.10	5.47	5.55	7.23	5.98	2.68	3.00
animal	N	15	15	15	15	15	5	5
BNT162a1		-	-	-	-	-	-	-
Group 3:	Mean	-1.61	8.05	4.29	13.15	10.98	4.97	6.24
10 µg/	SD	2.33	4.25	2.98	6.03	4.85	4.28	1.40
animal	N	15	15	15	15	15	5	5
BNT162a1		-	-	-	-	-	-	-
Group 4:	Mean	0.10	9.70	9.50	20.79	17.05	8.15	9.94
30 µg/	SD	1.86	6.04	5.44	6.86	7.25	4.69	3.49
animal	N	15	15	15	15	15	5	5
BNT162b1		-	-	-	-	-	-	-
Group 5:	Mean	-4.53	9.18	3.60	14.78	10.34	9.29	14.13
100 µg/	SD	1.76	3.72	2.76	7.38	6.39	4.90	8.65
animal	N	15	15	15	15	15	5	5
BNT162b1		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
Group 6:	Mean	-3.33	6.16	1.49	7.17	12.56	15.42	18.41
30 µg/	SD	4.18	4.77	4.56	4.28	9.66	4.01	6.20
animal	N	15	15	15	5	5	5	5
BNT162c1		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date						
		1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
Group 7:	Mean	-5.69	4.71	1.24	9.33	6.35	5.50	8.39
100 µg/	SD	2.59	2.91	2.99	3.95	3.85	1.76	4.16
animal	N	15	15	15	15	15	5	5
BNT162b2		-	-	-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 1: Control	Mean	8.60	11.89	13.91	18.28	17.10
	SD	3.84	3.96	4.64	3.49	5.13
	N	5	5	5	5	5
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	13.04	17.60	19.64	22.48	23.62
	SD	4.97	3.93	5.99	4.58	6.47
	N	5	5	5	5	5
		-	-	-	-	-
Group 3: 10 µg/ animal BNT162a1	Mean	8.49	13.76	14.00	15.28	15.77
	SD	1.12	2.54	2.81	2.36	1.50
	N	5	5	5	5	5
		-	-	-	-	-
Group 4: 30 µg/ animal BNT162b1	Mean	10.60	15.71	16.49	19.29	17.35
	SD	3.14	2.80	2.31	2.31	2.36
	N	5	5	5	5	5
		-	-	-	-	-
Group 5: 100 µg/ animal BNT162b1	Mean	20.92	21.76	21.04	24.59	24.62
	SD	10.19	5.26	5.58	3.52	3.78
	N	5	5	5	5	5
		-	-	-	-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date	
		9 → 29	9 → 30
Group 6:	Mean	23.79	21.15
30 µg/	SD	5.84	6.53
animal	N	5	5
BNT162c1		-	-

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TABLE 3-3 Body Weight Gain - Summary Rat

Body Weight Gain (%)

Sex: Female		Day(s) Relative to Start Date				
		16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
Group 7:	Mean	12.31	17.04	18.70	21.33	17.79
100 µg/	SD	3.99	4.14	4.41	4.12	4.74
animal	N	5	5	5	5	5
BNT162b2		-	-	-	-	-

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
1	1.7	17.4	21.0	35.4	35.7	-	-
2	0.6	17.0	18.3	31.0	33.0	-	-
3	3.3	22.5	25.2	41.2	43.4	-	-
4	3.6	18.8	21.5	34.5	36.0	-	-
5	2.1	19.6	21.3	31.7	33.7	-	-
6	3.0	19.1	22.0	41.5	42.9	-	-
7	3.2	19.1	23.5	36.0	37.5	-	-
8	0.9	16.5	20.5	31.7	33.6	-	-
9	3.0	24.3	28.5	46.5	47.2	-	-
10	1.0	19.8	24.4	33.7	34.8	-	-
11	2.2	16.9	20.3	31.0	34.4	0.2	3.8
12	2.6	9.5	12.4	34.2	38.4	-0.2	6.0
13	-1.1	14.0	18.8	30.4	31.3	2.7	8.4
14	1.1	15.9	18.3	31.3	32.4	2.2	4.2
15	3.6	19.2	24.3	38.5	42.9	1.6	8.5
Mean	2.06	17.97	21.34	35.25	37.14	1.29	6.19
SD	1.33	3.46	3.76	4.75	4.80	1.26	2.26
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
1	-	-	-	-	-
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	-	-	-	-	-
6	-	-	-	-	-
7	-	-	-	-	-
8	-	-	-	-	-
9	-	-	-	-	-
10	-	-	-	-	-
11	5.8	13.4	14.4	15.3	16.7
12	5.3	12.6	17.5	20.4	22.4
13	10.5	16.5	18.1	21.3	21.2
14	8.9	15.6	19.0	18.9	19.9
15	8.4	14.6	16.4	20.8	21.5
Mean	7.78	14.52	17.09	19.35	20.35
SD	2.20	1.57	1.80	2.43	2.22
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
31	-4.6	5.6	-0.9	14.7	7.8	-	-
32	-10.2	13.3	5.1	17.4	13.8	-	-
33	-1.2	19.1	13.1	35.6	24.6	-	-
34	-4.9	10.9	4.4	15.7	11.6	-	-
35	-4.4	12.0	6.8	21.9	16.3	-	-
36	-4.5	13.9	9.7	22.0	18.4	-	-
37	-5.2	9.8	4.7	18.5	14.2	-	-
38	-2.8	14.9	5.6	21.2	16.2	-	-
39	-7.8	7.7	-1.0	3.8	0.4	-	-
40	-3.5	9.2	3.6	15.4	10.2	-	-
41	-3.2	12.9	10.8	22.5	17.6	2.7	8.4
42	-2.9	10.7	5.1	18.9	14.3	3.9	11.4
43	-2.5	14.3	12.0	26.8	20.8	9.3	17.5
44	-3.0	12.3	5.9	25.6	20.6	3.3	10.5
45	-3.9	17.0	9.8	28.8	20.1	3.1	13.6
Mean	-4.30	12.23	6.31	20.60	15.14	4.46	12.27
SD	2.23	3.49	4.18	7.32	6.02	2.72	3.47
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
31	-	-	-	-	-
32	-	-	-	-	-
33	-	-	-	-	-
34	-	-	-	-	-
35	-	-	-	-	-
36	-	-	-	-	-
37	-	-	-	-	-
38	-	-	-	-	-
39	-	-	-	-	-
40	-	-	-	-	-
41	13.0	24.0	25.7	29.0	29.3
42	16.8	27.4	28.0	34.0	34.3
43	23.3	31.9	34.8	42.2	46.4
44	18.6	28.1	32.3	33.9	35.2
45	18.3	30.4	31.9	36.6	38.2
Mean	18.00	28.37	30.54	35.16	36.68
SD	3.69	3.00	3.62	4.80	6.31
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
61	-4.0	7.1	3.4	15.8	10.4	-	-
62	-5.8	8.7	-0.3	14.2	12.0	-	-
63	1.3	9.1	5.0	15.9	11.6	-	-
64	-4.0	6.5	0.3	11.5	10.3	-	-
65	-2.7	13.5	7.8	23.3	21.1	-	-
66	-5.4	1.5	-2.1	8.3	2.4	-	-
67	-3.2	11.9	4.6	17.6	14.0	-	-
68	-6.6	6.6	-1.9	10.3	3.9	-	-
69	-2.9	6.9	2.6	17.0	13.6	-	-
70	-3.1	11.0	3.6	14.8	11.3	-	-
71	-2.5	12.9	7.0	20.9	14.1	3.8	11.0
72	-2.5	8.9	5.3	18.1	14.2	2.7	10.4
73	-1.6	8.9	1.7	13.2	9.3	5.7	11.5
74	-4.6	8.8	0.8	14.3	12.6	5.4	11.1
75	-5.1	11.8	6.3	20.5	17.3	6.6	10.2
Mean	-3.51	8.94	2.93	15.71	11.87	4.84	10.86
SD	1.94	3.06	3.14	4.06	4.61	1.57	0.53
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
61	-	-	-	-	-
62	-	-	-	-	-
63	-	-	-	-	-
64	-	-	-	-	-
65	-	-	-	-	-
66	-	-	-	-	-
67	-	-	-	-	-
68	-	-	-	-	-
69	-	-	-	-	-
70	-	-	-	-	-
71	16.6	21.3	23.6	29.8	30.5
72	14.1	17.0	16.8	20.3	20.3
73	18.5	20.5	22.6	23.2	25.5
74	16.4	20.9	21.7	24.6	25.3
75	18.8	21.8	22.5	26.7	26.3
Mean	16.87	20.31	21.47	24.91	25.56
SD	1.90	1.92	2.68	3.60	3.64
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
91	-1.1	16.5	16.1	29.5	27.3	-	-
92	-2.8	16.5	14.1	24.6	22.6	-	-
93	-2.0	18.2	15.0	29.3	24.6	-	-
94	-1.6	12.8	11.1	22.9	23.9	-	-
95	-4.3	13.0	13.7	27.3	23.9	-	-
96	-3.4	16.4	14.3	33.9	29.2	-	-
97	-2.9	15.0	11.3	29.0	24.3	-	-
98	-1.1	16.0	14.9	28.7	26.4	-	-
99	-1.5	16.4	15.2	30.9	27.7	-	-
100	-3.8	13.3	7.9	22.3	17.1	-	-
101	-3.3	14.0	12.4	21.4	19.5	3.3	11.4
102	-4.4	15.4	12.3	32.2	28.2	6.7	9.4
103	-1.1	19.2	19.1	35.4	35.2	6.1	12.6
104	-1.9	16.5	12.2	28.4	23.9	7.4	12.1
105	-3.8	16.3	14.7	30.6	24.8	6.8	15.0
Mean	-2.61	15.71	13.63	28.43	25.24	6.06	12.10
SD	1.19	1.83	2.60	4.14	4.20	1.59	2.03
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
91	-	-	-	-	-
92	-	-	-	-	-
93	-	-	-	-	-
94	-	-	-	-	-
95	-	-	-	-	-
96	-	-	-	-	-
97	-	-	-	-	-
98	-	-	-	-	-
99	-	-	-	-	-
100	-	-	-	-	-
101	10.9	15.8	14.3	19.4	21.9
102	15.0	19.3	21.7	20.3	22.0
103	22.0	29.6	35.6	40.8	40.7
104	15.0	20.8	24.6	27.5	29.5
105	19.2	29.4	32.2	36.2	33.2
Mean	16.43	22.97	25.68	28.83	29.45
SD	4.31	6.22	8.45	9.49	7.98
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
121	-9.7	1.3	-4.3	11.3	7.7	-	-
122	-10.5	0.8	-7.1	6.5	1.3	-	-
123	-8.3	7.4	2.3	18.3	12.4	-	-
124	-3.6	8.7	5.2	20.8	16.5	-	-
125	-7.2	1.7	-4.0	10.2	6.0	-	-
126	-8.9	3.1	-1.6	14.7	10.1	-	-
127	-10.8	5.5	-2.8	14.4	7.5	-	-
128	-10.9	4.8	-5.5	12.1	1.3	-	-
129	-8.9	3.9	-3.9	8.5	2.0	-	-
130	-8.6	6.6	-2.4	18.2	9.5	-	-
131	-10.9	2.0	-5.1	10.6	3.2	7.5	13.3
132	-7.4	4.0	-5.7	11.6	2.8	8.9	14.0
133	-8.6	1.7	-7.7	8.4	0.8	10.6	16.8
134	-8.7	4.5	-2.4	12.5	5.9	6.1	11.3
135	-10.0	2.4	-7.4	7.8	2.3	6.0	12.1
Mean	-8.87	3.88	-3.50	12.41	5.95	7.83	13.49
SD	1.89	2.37	3.52	4.18	4.68	1.97	2.11
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
121	-	-	-	-	-
122	-	-	-	-	-
123	-	-	-	-	-
124	-	-	-	-	-
125	-	-	-	-	-
126	-	-	-	-	-
127	-	-	-	-	-
128	-	-	-	-	-
129	-	-	-	-	-
130	-	-	-	-	-
131	22.7	25.6	29.1	27.4	30.1
132	22.9	24.1	32.2	34.0	33.6
133	22.9	29.0	30.6	33.1	32.8
134	17.7	22.7	22.5	26.9	26.1
135	16.9	24.4	22.5	23.4	25.1
Mean	20.63	25.14	27.38	28.95	29.55
SD	3.04	2.37	4.60	4.47	3.84
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
151	-4.1	4.5	-2.3	-	-	-	-
152	-5.1	3.2	-2.3	-	-	-	-
153	-6.4	0.7	-3.6	-	-	-	-
154	-1.6	9.8	3.4	-	-	-	-
155	-4.7	6.3	2.1	-	-	-	-
156	-2.6	6.0	-1.1	-	-	-	-
157	-4.8	6.9	1.3	-	-	-	-
158	-7.8	-1.6	-6.8	-	-	-	-
159	-1.4	8.4	5.5	-	-	-	-
160	-7.4	4.8	-4.0	-	-	-	-
161	-4.4	5.6	-1.9	11.1	19.8	23.3	24.0
162	-6.8	3.5	-3.4	9.2	11.1	17.2	24.5
163	-4.7	9.7	3.6	10.1	17.4	22.8	26.7
164	-7.5	3.3	-4.9	9.1	13.3	20.0	25.3
165	-2.5	12.1	2.8	10.6	16.8	26.8	31.9
Mean	-4.79	5.54	-0.77	10.03	15.69	22.03	26.48
SD	2.10	3.57	3.63	0.87	3.43	3.63	3.18
N	15	15	15	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date	
	9 → 29	9 → 30
151	-	-
152	-	-
153	-	-
154	-	-
155	-	-
156	-	-
157	-	-
158	-	-
159	-	-
160	-	-
161	23.1	25.0
162	28.5	26.4
163	26.4	27.8
164	28.0	29.0
165	31.1	31.2
Mean	27.42	27.88
SD	2.94	2.36
N	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
181	-3.2	5.0	-1.7	9.8	4.5	-	-
182	-10.0	2.8	-6.4	9.0	1.0	-	-
183	-10.1	6.5	-2.6	13.8	6.3	-	-
184	-8.2	6.0	-1.9	14.1	6.6	-	-
185	-8.8	3.3	-6.7	11.5	3.6	-	-
186	-7.9	5.8	-6.6	11.5	5.4	-	-
187	-8.7	2.9	-8.1	6.6	-1.8	-	-
188	-7.3	5.4	-2.3	17.6	8.8	-	-
189	-8.7	2.4	-7.5	10.0	3.7	-	-
190	-8.2	6.1	-0.2	16.5	10.7	-	-
191	-5.9	3.4	-4.5	11.7	4.9	2.2	10.2
192	-6.2	2.9	-2.4	11.2	6.4	3.1	9.6
193	-4.0	4.5	-1.2	12.0	8.7	3.3	8.6
194	-7.0	2.2	-6.1	9.1	-0.4	8.4	17.7
195	-5.7	1.9	-2.9	11.0	4.0	6.4	14.0
Mean	-7.34	4.06	-4.07	11.69	4.82	4.69	12.02
SD	2.02	1.61	2.59	2.88	3.41	2.59	3.78
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Male Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
181	-	-	-	-	-
182	-	-	-	-	-
183	-	-	-	-	-
184	-	-	-	-	-
185	-	-	-	-	-
186	-	-	-	-	-
187	-	-	-	-	-
188	-	-	-	-	-
189	-	-	-	-	-
190	-	-	-	-	-
191	17.8	22.4	25.9	27.4	31.1
192	15.2	17.8	21.2	24.3	23.6
193	16.1	19.9	22.9	24.3	25.5
194	23.4	28.3	28.9	29.8	32.7
195	18.6	25.6	27.4	29.6	31.6
Mean	18.21	22.80	25.27	27.09	28.90
SD	3.18	4.24	3.17	2.73	4.10
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
16	4.7	13.6	12.0	21.9	22.6	-	-
17	3.5	18.2	24.0	22.3	21.7	-	-
18	2.4	6.3	10.6	18.1	18.3	-	-
19	0.5	7.1	8.4	17.9	14.8	-	-
20	-0.4	7.0	6.5	14.1	14.4	-	-
21	0.7	13.1	11.6	16.1	17.6	-	-
22	0.9	6.9	11.0	14.2	13.4	-	-
23	1.4	7.7	10.6	17.6	17.7	-	-
24	2.4	9.1	11.6	18.7	20.3	-	-
25	1.6	11.3	11.7	16.2	17.2	-	-
26	-0.9	3.6	4.0	10.8	9.6	1.7	9.2
27	3.7	8.0	15.3	21.0	14.4	11.1	12.7
28	0.7	13.1	15.1	19.5	22.0	-0.4	2.8
29	-3.1	8.5	12.9	16.5	12.7	7.6	8.0
30	1.7	4.2	9.6	20.1	13.8	9.5	7.4
Mean	1.32	9.19	11.67	17.66	16.70	5.88	8.00
SD	1.94	3.95	4.48	3.15	3.82	5.01	3.56
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 1: Control	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
16	-	-	-	-	-
17	-	-	-	-	-
18	-	-	-	-	-
19	-	-	-	-	-
20	-	-	-	-	-
21	-	-	-	-	-
22	-	-	-	-	-
23	-	-	-	-	-
24	-	-	-	-	-
25	-	-	-	-	-
26	5.6	7.5	6.0	13.4	10.1
27	11.8	17.4	17.9	21.2	21.4
28	4.1	8.6	14.1	21.5	22.2
29	13.0	13.4	16.2	16.1	18.0
30	8.5	12.5	15.4	19.3	13.7
Mean	8.60	11.89	13.91	18.28	17.10
SD	3.84	3.96	4.64	3.49	5.13
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
46	-3.4	7.7	4.6	9.4	4.0	-	-
47	-4.8	9.4	7.3	11.2	8.3	-	-
48	-0.6	11.7	11.4	26.0	23.6	-	-
49	-1.8	8.0	0.1	14.7	6.7	-	-
50	-4.0	2.3	4.0	13.1	8.8	-	-
51	-3.6	13.8	1.4	13.5	5.7	-	-
52	-0.1	12.6	12.7	31.6	19.6	-	-
53	0.8	14.7	10.5	23.2	12.7	-	-
54	-4.3	7.7	2.5	9.2	4.8	-	-
55	-3.7	10.7	4.0	13.8	9.6	-	-
56	1.0	12.2	10.2	22.1	15.3	4.6	6.3
57	-1.9	9.7	7.6	17.6	10.8	9.3	10.5
58	0.1	8.0	3.0	13.0	5.8	8.8	14.3
59	0.8	20.3	14.5	21.1	12.9	8.4	8.3
60	-3.7	-3.5	-6.5	4.8	2.0	3.5	9.0
Mean	-1.94	9.69	5.83	16.29	10.04	6.92	9.68
SD	2.10	5.47	5.55	7.23	5.98	2.68	3.00
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
46	-	-	-	-	-
47	-	-	-	-	-
48	-	-	-	-	-
49	-	-	-	-	-
50	-	-	-	-	-
51	-	-	-	-	-
52	-	-	-	-	-
53	-	-	-	-	-
54	-	-	-	-	-
55	-	-	-	-	-
56	14.0	24.5	27.8	24.4	26.1
57	11.4	15.1	13.9	16.0	15.3
58	20.8	17.1	22.7	27.4	32.5
59	11.7	15.8	20.0	24.9	24.2
60	7.3	15.5	13.8	19.7	20.1
Mean	13.04	17.60	19.64	22.48	23.62
SD	4.97	3.93	5.99	4.58	6.47
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
76	-5.6	10.0	3.3	19.3	16.0	-	-
77	-2.4	6.0	2.0	7.8	3.6	-	-
78	-3.8	8.6	5.9	14.9	8.9	-	-
79	-1.9	7.0	4.2	15.1	12.9	-	-
80	-2.5	3.3	2.1	6.7	8.6	-	-
81	1.4	19.0	12.8	11.9	14.6	-	-
82	-3.8	11.8	7.3	11.7	11.6	-	-
83	1.0	11.0	5.3	12.2	11.0	-	-
84	0.6	9.3	4.9	17.2	15.1	-	-
85	2.4	9.2	3.1	13.3	10.8	-	-
86	-4.0	3.0	1.5	4.8	3.1	6.2	7.3
87	-3.0	8.2	3.7	29.7	21.9	11.7	4.4
88	-2.2	2.9	1.4	9.9	7.3	1.6	5.8
89	0.6	3.5	1.5	9.0	7.9	4.3	5.7
90	-1.0	8.0	5.4	13.7	11.5	1.0	7.9
Mean	-1.61	8.05	4.29	13.15	10.98	4.97	6.24
SD	2.33	4.25	2.98	6.03	4.85	4.28	1.40
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
76	-	-	-	-	-
77	-	-	-	-	-
78	-	-	-	-	-
79	-	-	-	-	-
80	-	-	-	-	-
81	-	-	-	-	-
82	-	-	-	-	-
83	-	-	-	-	-
84	-	-	-	-	-
85	-	-	-	-	-
86	10.0	13.7	14.1	17.0	17.4
87	7.0	11.0	13.9	11.5	13.6
88	9.0	15.6	9.5	15.8	16.3
89	8.2	16.9	15.4	14.8	15.0
90	8.3	11.5	17.0	17.3	16.6
Mean	8.49	13.76	14.00	15.28	15.77
SD	1.12	2.54	2.81	2.36	1.50
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
106	-1.2	10.1	8.3	29.0	24.8	-	-
107	0.2	9.4	7.2	12.1	10.2	-	-
108	-1.3	15.2	13.1	20.2	17.6	-	-
109	1.1	18.5	21.2	36.2	35.0	-	-
110	0.1	-0.4	4.0	15.7	16.0	-	-
111	2.6	10.6	11.8	17.1	16.3	-	-
112	-2.0	-0.6	9.5	14.4	13.7	-	-
113	-1.0	16.1	14.0	28.2	22.8	-	-
114	0.5	10.1	8.3	22.2	14.4	-	-
115	3.8	12.9	8.4	20.3	20.3	-	-
116	2.1	6.8	8.8	23.1	14.0	11.1	11.8
117	-0.7	7.0	4.2	15.9	12.9	7.4	10.3
118	0.9	18.6	18.0	27.4	22.8	0.5	5.9
119	-3.4	3.0	0.6	13.5	6.6	12.5	14.5
120	-0.2	7.9	5.1	16.7	8.4	9.2	7.2
Mean	0.10	9.70	9.50	20.79	17.05	8.15	9.94
SD	1.86	6.04	5.44	6.86	7.25	4.69	3.49
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
106	-	-	-	-	-
107	-	-	-	-	-
108	-	-	-	-	-
109	-	-	-	-	-
110	-	-	-	-	-
111	-	-	-	-	-
112	-	-	-	-	-
113	-	-	-	-	-
114	-	-	-	-	-
115	-	-	-	-	-
116	9.9	14.3	17.7	19.4	18.5
117	6.8	12.5	12.8	16.6	16.2
118	8.6	14.9	17.7	18.4	17.4
119	13.6	19.8	18.5	22.9	20.4
120	14.1	17.1	15.7	19.2	14.2
Mean	10.60	15.71	16.49	19.29	17.35
SD	3.14	2.80	2.31	2.31	2.36
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
136	-3.7	10.4	6.0	24.6	20.1	-	-
137	-5.1	13.4	6.1	16.6	10.4	-	-
138	-1.2	4.9	2.1	10.2	6.3	-	-
139	-5.1	7.4	5.6	11.0	13.2	-	-
140	-2.0	10.2	4.4	13.2	12.3	-	-
141	-6.1	6.1	2.2	5.7	-0.4	-	-
142	-4.4	11.7	3.2	15.0	10.4	-	-
143	-3.8	8.4	5.4	24.1	21.3	-	-
144	-7.8	15.6	7.7	29.6	18.4	-	-
145	-4.6	8.3	2.6	8.9	6.0	-	-
146	-2.4	13.7	2.8	11.9	7.1	15.4	26.8
147	-6.5	3.2	-1.1	8.1	5.7	4.8	7.6
148	-5.7	11.2	3.1	21.2	10.7	3.8	7.6
149	-4.1	9.6	6.2	17.0	12.9	10.7	19.4
150	-5.3	3.6	-2.4	4.6	0.8	11.8	9.2
Mean	-4.53	9.18	3.60	14.78	10.34	9.29	14.13
SD	1.76	3.72	2.76	7.38	6.39	4.90	8.65
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
136	-	-	-	-	-
137	-	-	-	-	-
138	-	-	-	-	-
139	-	-	-	-	-
140	-	-	-	-	-
141	-	-	-	-	-
142	-	-	-	-	-
143	-	-	-	-	-
144	-	-	-	-	-
145	-	-	-	-	-
146	35.9	28.0	28.4	29.1	28.7
147	10.1	15.0	12.8	19.4	19.3
148	16.7	18.5	20.3	25.2	23.2
149	26.3	25.7	22.4	23.6	24.0
150	15.6	21.6	21.3	25.7	27.8
Mean	20.92	21.76	21.04	24.59	24.62
SD	10.19	5.26	5.58	3.52	3.78
N	5	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	9 → 15	9 → 18	9 → 22	9 → 25
166	2.3	9.6	6.0	-	-	-	-
167	-5.9	6.7	2.5	-	-	-	-
168	-8.4	-0.8	-2.3	-	-	-	-
169	1.0	14.6	7.9	-	-	-	-
170	-2.9	3.2	1.1	-	-	-	-
171	4.3	-2.2	6.3	-	-	-	-
172	-2.1	6.2	-2.6	-	-	-	-
173	-7.3	-0.5	-9.1	-	-	-	-
174	-6.1	3.2	-1.2	-	-	-	-
175	-6.0	9.5	2.5	-	-	-	-
176	-1.1	9.7	1.4	7.2	12.5	16.9	23.6
177	1.6	8.2	3.3	12.1	26.3	18.8	23.4
178	-6.1	8.3	1.5	3.8	6.0	12.8	13.2
179	-9.2	5.7	-2.4	10.7	16.6	18.9	21.5
180	-4.1	10.9	7.5	2.1	1.4	9.8	10.4
Mean	-3.33	6.16	1.49	7.17	12.56	15.42	18.41
SD	4.18	4.77	4.56	4.28	9.66	4.01	6.20
N	15	15	15	5	5	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date	
	9 → 29	9 → 30
166	-	-
167	-	-
168	-	-
169	-	-
170	-	-
171	-	-
172	-	-
173	-	-
174	-	-
175	-	-
176	27.8	25.6
177	24.7	24.6
178	21.3	15.7
179	30.0	27.2
180	15.1	12.6
Mean	23.79	21.15
SD	5.84	6.53
N	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 → 2	1 → 8	1 → 9	1 → 15	1 → 16	16 → 18	16 → 22
196	-3.9	2.7	2.1	12.6	12.0	-	-
197	-2.0	10.3	4.2	5.9	8.2	-	-
198	-4.7	10.5	5.6	13.8	9.5	-	-
199	-12.1	3.1	-3.8	11.8	2.6	-	-
200	-7.2	0.9	-1.9	4.0	0.5	-	-
201	-7.5	6.8	2.8	15.5	5.7	-	-
202	-5.5	6.6	0.7	2.4	3.4	-	-
203	-7.7	3.3	0.6	7.9	4.7	-	-
204	-3.6	5.9	6.9	4.6	8.3	-	-
205	-6.5	3.1	0.3	7.7	1.7	-	-
206	-6.7	2.2	-2.4	11.3	4.5	6.2	8.6
207	-5.9	1.6	-1.4	8.4	7.1	6.3	7.3
208	-1.4	3.6	3.2	12.4	14.8	2.4	1.9
209	-4.9	5.7	1.8	8.5	6.7	6.4	11.8
210	-5.8	4.3	-0.1	12.9	5.5	6.1	12.2
Mean	-5.69	4.71	1.24	9.33	6.35	5.50	8.39
SD	2.59	2.91	2.99	3.95	3.85	1.76	4.16
N	15	15	15	15	15	5	5

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TABLE 3-4 Body Weight Gain - Individual Data Rat

Sex: Female Body Weight Gain (%)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	16 → 25	16 → 29	16 → 32	16 → 36	16 → 37
196	-	-	-	-	-
197	-	-	-	-	-
198	-	-	-	-	-
199	-	-	-	-	-
200	-	-	-	-	-
201	-	-	-	-	-
202	-	-	-	-	-
203	-	-	-	-	-
204	-	-	-	-	-
205	-	-	-	-	-
206	13.1	17.5	20.7	21.0	16.4
207	11.2	16.5	17.8	20.3	18.6
208	6.1	10.4	11.4	15.1	10.5
209	14.6	20.1	21.9	25.3	20.5
210	16.5	20.8	21.8	24.9	22.9
Mean	12.31	17.04	18.70	21.33	17.79
SD	3.99	4.14	4.41	4.12	4.74
N	5	5	5	5	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 1: Control	Day(s) Relative to Start Date			
	10	17	31	38
1	-	313.8	-	-
2	-	307.2	-	-
3	-	335.8	-	-
4	-	333.3	-	-
5	-	310.4	-	-
6	-	333.0	-	-
7	-	318.0	-	-
8	-	335.2	-	-
9	-	340.4	-	-
10	-	338.5	-	-
11	-	-	-	382.3
12	-	-	-	388.0
13	-	-	-	407.3
14	-	-	-	357.4
15	-	-	-	406.3
Mean	-	326.56	-	388.26
SD	-	12.71	-	20.47
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
31	-	270.6	-	-
32	-	257.9	-	-
33	-	299.9	-	-
34	-	281.6	-	-
35	-	280.0	-	-
36	-	267.5	-	-
37	-	272.7	-	-
38	-	281.9	-	-
39	-	236.4	-	-
40	-	270.3	-	-
41	-	-	-	355.1
42	-	-	-	355.8
43	-	-	-	417.0
44	-	-	-	377.4
45	-	-	-	378.2
Mean	-	271.88	-	376.70
SD	-	16.75	-	25.15
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
61	-	350.3	-	-
62	-	302.2	-	-
63	-	344.3	-	-
64	-	323.3	-	-
65	-	336.8	-	-
66	-	320.4	-	-
67	-	355.1	-	-
68	-	277.7	-	-
69	-	313.5	-	-
70	-	354.3	-	-
71	-	-	-	410.7
72	-	-	-	376.6
73	-	-	-	366.9
74	-	-	-	422.0
75	-	-	-	442.8
Mean	-	327.79	-	403.80
SD	-	25.28	-	31.63
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
91	-	307.3	-	-
92	-	290.0	-	-
93	-	299.9	-	-
94	-	289.3	-	-
95	-	302.5	-	-
96	-	331.1	-	-
97	-	301.6	-	-
98	-	287.8	-	-
99	-	320.2	-	-
100	-	297.9	-	-
101	-	-	-	359.7
102	-	-	-	373.6
103	-	-	-	451.4
104	-	-	-	387.1
105	-	-	-	405.8
Mean	-	302.76	-	395.52
SD	-	13.86	-	35.58
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
121	-	331.9	-	-
122	-	272.1	-	-
123	-	306.9	-	-
124	-	363.7	-	-
125	-	289.6	-	-
126	-	340.9	-	-
127	-	303.9	-	-
128	-	277.5	-	-
129	-	301.0	-	-
130	-	301.1	-	-
131	-	-	-	420.9
132	-	-	-	374.8
133	-	-	-	361.8
134	-	-	-	402.4
135	-	-	-	376.2
Mean	-	308.86	-	387.22
SD	-	28.72	-	23.91
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	10	17	31	38
151	261.1	-	-	-
152	303.3	-	-	-
153	250.9	-	-	-
154	276.8	-	-	-
155	282.0	-	-	-
156	265.4	-	-	-
157	296.3	-	-	-
158	245.8	-	-	-
159	279.9	-	-	-
160	253.9	-	-	-
161	-	-	374.8	-
162	-	-	327.9	-
163	-	-	391.8	-
164	-	-	349.7	-
165	-	-	388.2	-
Mean	271.54	-	366.48	-
SD	19.37	-	27.17	-
N	10	-	5	-

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Male Body Weight at Autopsy (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date			
	10	17	31	38
181	-	329.3	-	-
182	-	271.5	-	-
183	-	294.8	-	-
184	-	292.7	-	-
185	-	337.6	-	-
186	-	263.2	-	-
187	-	300.6	-	-
188	-	305.9	-	-
189	-	293.2	-	-
190	-	300.8	-	-
191	-	-	-	356.9
192	-	-	-	389.1
193	-	-	-	410.6
194	-	-	-	336.7
195	-	-	-	391.4
Mean	-	298.96	-	376.94
SD	-	22.58	-	29.63
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 1: Control	Day(s) Relative to Start Date			
	10	17	31	38
16	-	233.2	-	-
17	-	218.5	-	-
18	-	203.8	-	-
19	-	216.8	-	-
20	-	225.5	-	-
21	-	216.0	-	-
22	-	207.2	-	-
23	-	217.6	-	-
24	-	237.1	-	-
25	-	229.6	-	-
26	-	-	-	243.0
27	-	-	-	275.4
28	-	-	-	292.6
29	-	-	-	252.4
30	-	-	-	254.0
Mean	-	220.53	-	263.48
SD	-	10.78	-	20.14
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
46	-	212.9	-	-
47	-	215.9	-	-
48	-	220.2	-	-
49	-	206.1	-	-
50	-	213.3	-	-
51	-	193.3	-	-
52	-	207.1	-	-
53	-	198.6	-	-
54	-	207.6	-	-
55	-	209.4	-	-
56	-	-	-	248.5
57	-	-	-	246.3
58	-	-	-	275.8
59	-	-	-	262.4
60	-	-	-	249.6
Mean	-	208.44	-	256.52
SD	-	7.97	-	12.48
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date			
	10	17	31	38
76	-	214.4	-	-
77	-	214.7	-	-
78	-	204.5	-	-
79	-	246.9	-	-
80	-	190.0	-	-
81	-	213.4	-	-
82	-	253.3	-	-
83	-	207.4	-	-
84	-	213.9	-	-
85	-	211.6	-	-
86	-	-	-	238.4
87	-	-	-	262.7
88	-	-	-	284.0
89	-	-	-	246.9
90	-	-	-	229.9
Mean	-	217.01	-	252.38
SD	-	19.01	-	21.43
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
106	-	233.3	-	-
107	-	231.4	-	-
108	-	216.4	-	-
109	-	261.4	-	-
110	-	232.2	-	-
111	-	248.3	-	-
112	-	210.9	-	-
113	-	245.2	-	-
114	-	212.2	-	-
115	-	219.8	-	-
116	-	-	-	256.8
117	-	-	-	253.4
118	-	-	-	273.4
119	-	-	-	258.8
120	-	-	-	249.6
Mean	-	231.11	-	258.40
SD	-	16.76	-	9.09
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date			
	10	17	31	38
136	-	245.4	-	-
137	-	212.3	-	-
138	-	254.9	-	-
139	-	226.8	-	-
140	-	209.9	-	-
141	-	240.7	-	-
142	-	205.9	-	-
143	-	227.9	-	-
144	-	243.8	-	-
145	-	240.9	-	-
146	-	-	-	238.8
147	-	-	-	251.1
148	-	-	-	243.2
149	-	-	-	278.6
150	-	-	-	257.9
Mean	-	230.85	-	253.92
SD	-	16.95	-	15.62
N	-	10	-	5

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date			
	10	17	31	38
166	192.1	-	-	-
167	201.7	-	-	-
168	174.9	-	-	-
169	196.4	-	-	-
170	225.0	-	-	-
171	192.7	-	-	-
172	190.2	-	-	-
173	183.2	-	-	-
174	187.6	-	-	-
175	204.0	-	-	-
176	-	-	221.1	-
177	-	-	235.9	-
178	-	-	224.7	-
179	-	-	233.5	-
180	-	-	285.9	-
Mean	194.78	-	240.22	-
SD	13.59	-	26.25	-
N	10	-	5	-

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TABLE 3-5 Body Weight at Autopsy - Individual Data Rat

Sex: Female Body Weight at Autopsy (g)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date			
	10	17	31	38
196	-	248.5	-	-
197	-	205.9	-	-
198	-	200.7	-	-
199	-	195.0	-	-
200	-	248.7	-	-
201	-	211.3	-	-
202	-	203.1	-	-
203	-	225.1	-	-
204	-	234.5	-	-
205	-	213.1	-	-
206	-	-	-	236.3
207	-	-	-	247.4
208	-	-	-	238.7
209	-	-	-	241.1
210	-	-	-	261.7
Mean	-	218.59	-	245.04
SD	-	19.60	-	10.19
N	-	10	-	5

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Male		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 1:	Mean	95.02	89.37	79.37	74.29	71.17
Control	SD	4.58	3.07	3.18	2.75	4.85
	N	15	15	5	5	5
		-	-	-	-	-
Group 2:	Mean	89.60*	82.93**	78.47	85.90**	78.78**
30 µg/	SD	5.50	4.86	3.15	3.32	2.09
animal	N	15	15	5	5	5
BNT162a1	%Diff	-5.7	-7.2	-1.1	15.6	10.7
Group 3:	Mean	78.93**	80.15**	70.54**	69.89	70.18
10 µg/	SD	4.99	5.23	4.92	4.87	3.36
animal	N	15	15	5	5	5
BNT162a1	%Diff	-16.9	-10.3	-11.1	-5.9	-1.4
Group 4:	Mean	90.88	87.19	74.95	76.22	70.46
30 µg/	SD	5.24	4.51	2.05	4.45	3.44
animal	N	15	15	5	5	5
BNT162b1	%Diff	-4.4	-2.4	-5.6	2.6	-1.0

Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Male		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 5:	Mean	73.25**	78.44**	69.61**	74.13	70.34
100 µg/	SD	5.22	4.70	3.06	7.97	1.75
animal	N	15	15	5	5	5
BNT162b1	%Diff	-22.9	-12.2	-12.3	-0.2	-1.2
Group 6:	Mean	77.41**	77.14**	74.10	72.39	-
30 µg/	SD	2.78	2.41	3.86	5.35	-
animal	N	15	5	5	5	-
BNT162c1	%Diff	-18.5	-13.7	-6.6	-2.6	-
Group 7:	Mean	73.79**	79.48**	68.70**	78.21	71.79
100 µg/	SD	5.13	6.12	3.17	5.55	3.43
animal	N	15	15	5	5	5
BNT162b2	%Diff	-22.3	-11.1	-13.4	5.3	0.9

Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Female		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 1:	Mean	98.30	94.31	82.23	85.56	81.65
Control	SD	6.46	5.55	5.07	6.08	5.64
	N	15	15	5	5	5
	-	-	-	-	-	-
Group 2:	Mean	95.08	90.19	83.01	88.56	85.17
30 µg/	SD	6.23	7.02	5.39	5.41	2.09
animal	N	15	15	5	5	5
BNT162a1	%Diff	-3.3	-4.4	0.9	3.5	4.3
Group 3:	Mean	91.92*	93.16	85.45	88.77	81.33
10 µg/	SD	6.28	6.42	9.00	6.33	5.85
animal	N	15	15	5	5	5
BNT162a1	%Diff	-6.5	-1.2	3.9	3.8	-0.4
Group 4:	Mean	96.59	93.89	81.64	84.09	79.63
30 µg/	SD	6.84	6.67	6.27	3.65	3.75
animal	N	15	15	5	5	5
BNT162b1	%Diff	-1.7	-0.4	-0.7	-1.7	-2.5

Anova & Dunnett: * = $p \leq 0.05$

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TABLE 4-1 Food Consumption - Summary Rat

Relative Food Consumption (g/kg b.w./day)

Sex: Female		Day(s) Relative to Start Date				
		TW 1	TW 2	TW 3	TW 4	TW 5
Group 5:	Mean	85.20**	92.31	86.22	96.32*	80.15
100 µg/	SD	7.16	5.32	4.66	6.53	6.97
animal	N	15	15	5	5	5
BNT162b1	%Diff	-13.3	-2.1	4.9	12.6	-1.8
Group 6:	Mean	88.75**	91.99	88.83	88.76	-
30 µg/	SD	5.68	5.49	7.46	3.90	-
animal	N	15	5	5	5	-
BNT162c1	%Diff	-9.7	-2.5	8.0	3.7	-
Group 7:	Mean	84.82**	92.22	85.38	96.84**	85.75
100 µg/	SD	5.22	5.49	4.86	1.80	3.65
animal	N	15	15	5	5	5
BNT162b2	%Diff	-13.7	-2.2	3.8	13.2	5.0

Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 4-1 Food Consumption - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Relative Food Consumption	2	Male	TW 1	*	Anova & Dunnett: * = p ≤ 0.05
	Relative Food Consumption	2	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	2	Male	TW 4	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	2	Male	TW 5	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	3	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	3	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	3	Male	TW 3	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Male	TW 3	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	6	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	6	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Male	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Male	TW 2	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Male	TW 3	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 4-1 Food Consumption - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Relative Food Consumption	3	Female	TW 1	*	Anova & Dunnett: * = p ≤ 0.05
	Relative Food Consumption	5	Female	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	5	Female	TW 4	*	Anova & Dunnett: * = p ≤ 0.05
	Relative Food Consumption	6	Female	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Female	TW 1	**	Anova & Dunnett: ** = p ≤ 0.01
	Relative Food Consumption	7	Female	TW 4	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 1: Control	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
1	95.1	89.9	-	-	-
2	97.3	92.4	-	-	-
3	97.6	88.0	-	-	-
4	88.9	87.0	-	-	-
5	99.6	90.9	-	-	-
6	105.0	96.5	-	-	-
7	94.3	84.9	-	-	-
8	88.0	86.9	-	-	-
9	97.1	93.0	-	-	-
10	96.4	88.7	-	-	-
11	96.5	87.6	75.7	70.8	72.6
12	94.2	91.8	82.0	77.8	75.7
13	88.3	85.9	76.1	72.9	62.9
14	96.2	88.5	81.7	73.8	72.4
15	90.9	88.7	81.3	76.1	72.4
Mean	95.02	89.37	79.37	74.29	71.17
SD	4.58	3.07	3.18	2.75	4.85
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
31	80.5	80.3	-	-	-
32	92.0	79.7	-	-	-
33	94.8	84.2	-	-	-
34	84.9	77.1	-	-	-
35	97.7	88.0	-	-	-
36	87.7	84.6	-	-	-
37	83.8	82.3	-	-	-
38	88.1	82.1	-	-	-
39	87.4	72.5	-	-	-
40	86.3	81.5	-	-	-
41	99.6	93.6	81.1	86.1	79.7
42	94.6	86.2	80.1	85.6	81.4
43	93.7	83.1	80.3	85.5	77.3
44	88.1	86.4	77.3	90.8	79.3
45	84.8	82.4	73.4	81.5	76.1
Mean	89.60	82.93	78.47	85.90	78.78
SD	5.50	4.86	3.15	3.32	2.09
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
61	75.0	73.5	-	-	-
62	74.6	82.6	-	-	-
63	75.9	75.1	-	-	-
64	75.1	79.5	-	-	-
65	87.4	87.5	-	-	-
66	77.1	78.2	-	-	-
67	76.8	78.3	-	-	-
68	74.6	73.1	-	-	-
69	84.5	87.9	-	-	-
70	76.3	77.2	-	-	-
71	82.8	83.3	66.8	67.3	71.8
72	88.9	84.9	70.5	76.9	68.7
73	81.6	86.9	77.9	64.1	75.3
74	73.3	73.3	65.4	72.0	67.2
75	79.7	81.1	72.1	69.1	67.9
Mean	78.93	80.15	70.54	69.89	70.18
SD	4.99	5.23	4.92	4.87	3.36
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
91	93.4	88.5	-	-	-
92	89.5	84.9	-	-	-
93	91.3	89.5	-	-	-
94	101.3	95.6	-	-	-
95	93.2	87.0	-	-	-
96	87.4	84.5	-	-	-
97	85.2	82.4	-	-	-
98	100.2	93.4	-	-	-
99	85.0	85.6	-	-	-
100	87.7	86.5	-	-	-
101	91.6	89.6	75.9	79.3	71.8
102	96.0	92.8	77.1	76.4	68.2
103	89.3	83.3	75.1	77.7	74.2
104	83.8	78.5	71.6	68.5	65.7
105	88.2	85.8	75.0	79.1	72.4
Mean	90.88	87.19	74.95	76.22	70.46
SD	5.24	4.51	2.05	4.45	3.44
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
121	66.5	72.3	-	-	-
122	67.7	75.8	-	-	-
123	71.9	81.1	-	-	-
124	78.3	74.9	-	-	-
125	76.1	83.5	-	-	-
126	75.7	82.0	-	-	-
127	74.9	86.9	-	-	-
128	73.3	81.5	-	-	-
129	72.0	71.0	-	-	-
130	76.9	79.3	-	-	-
131	68.4	71.4	67.2	64.6	68.9
132	85.7	81.9	68.7	84.3	71.7
133	71.7	80.5	75.0	73.2	72.6
134	74.4	78.1	68.8	68.8	68.5
135	65.2	76.4	68.3	79.7	69.9
Mean	73.25	78.44	69.61	74.13	70.34
SD	5.22	4.70	3.06	7.97	1.75
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
151	77.2	-	-	-	-
152	77.5	-	-	-	-
153	72.7	-	-	-	-
154	81.1	-	-	-	-
155	81.5	-	-	-	-
156	77.3	-	-	-	-
157	73.4	-	-	-	-
158	78.1	-	-	-	-
159	81.8	-	-	-	-
160	78.7	-	-	-	-
161	79.4	80.0	78.0	64.5	-
162	76.6	76.3	68.4	69.7	-
163	74.6	73.5	72.2	73.6	-
164	75.4	77.9	75.3	76.9	-
165	76.1	77.9	76.7	77.2	-
Mean	77.41	77.14	74.10	72.39	-
SD	2.78	2.41	3.86	5.35	-
N	15	5	5	5	-

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Male Relative Food Consumption (g/kg b.w./day)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
181	63.1	70.9	-	-	-
182	68.6	77.0	-	-	-
183	76.3	76.0	-	-	-
184	79.3	87.4	-	-	-
185	69.6	74.3	-	-	-
186	80.1	90.9	-	-	-
187	67.1	71.1	-	-	-
188	79.6	85.1	-	-	-
189	73.0	78.4	-	-	-
190	78.9	86.7	-	-	-
191	75.1	81.7	66.6	82.7	72.3
192	72.1	77.2	66.8	75.7	66.2
193	78.3	83.0	72.7	83.7	73.5
194	72.5	73.4	65.8	78.9	71.5
195	73.1	79.1	71.5	70.1	75.4
Mean	73.79	79.48	68.70	78.21	71.79
SD	5.13	6.12	3.17	5.55	3.43
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 1: Control	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
16	105.2	98.1	-	-	-
17	107.6	98.6	-	-	-
18	105.2	92.7	-	-	-
19	91.1	89.2	-	-	-
20	94.4	91.8	-	-	-
21	98.2	86.9	-	-	-
22	111.5	107.9	-	-	-
23	93.3	91.7	-	-	-
24	97.9	90.4	-	-	-
25	95.2	87.1	-	-	-
26	90.8	98.7	84.4	91.6	89.2
27	96.1	92.5	78.6	77.8	75.2
28	95.7	93.8	87.5	80.4	84.0
29	91.3	96.5	85.3	89.3	77.0
30	101.0	98.8	75.3	88.8	82.8
Mean	98.30	94.31	82.23	85.56	81.65
SD	6.46	5.55	5.07	6.08	5.64
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
46	101.4	82.9	-	-	-
47	93.6	96.2	-	-	-
48	100.1	100.9	-	-	-
49	82.6	79.0	-	-	-
50	97.5	86.0	-	-	-
51	82.9	86.9	-	-	-
52	97.9	95.8	-	-	-
53	99.4	86.7	-	-	-
54	97.8	96.4	-	-	-
55	96.0	94.4	-	-	-
56	89.4	87.2	79.6	86.1	85.3
57	101.9	102.5	89.2	97.4	87.0
58	89.4	82.7	84.8	83.0	82.1
59	97.4	87.5	75.6	87.2	84.4
60	98.8	87.6	85.8	89.0	87.2
Mean	95.08	90.19	83.01	88.56	85.17
SD	6.23	7.02	5.39	5.41	2.09
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
76	88.1	105.6	-	-	-
77	86.6	89.2	-	-	-
78	99.4	98.0	-	-	-
79	94.8	96.9	-	-	-
80	87.0	94.3	-	-	-
81	99.0	83.8	-	-	-
82	82.3	90.2	-	-	-
83	88.7	90.9	-	-	-
84	95.0	97.6	-	-	-
85	91.5	91.6	-	-	-
86	89.8	86.7	77.9	88.0	77.9
87	97.4	101.9	95.9	82.6	78.1
88	81.2	82.1	74.6	85.1	75.6
89	96.7	95.0	91.4	99.2	89.1
90	101.2	93.6	87.6	89.0	86.0
Mean	91.92	93.16	85.45	88.77	81.33
SD	6.28	6.42	9.00	6.33	5.85
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
106	89.8	90.1	-	-	-
107	91.9	89.8	-	-	-
108	99.4	100.2	-	-	-
109	91.7	100.5	-	-	-
110	85.3	88.2	-	-	-
111	94.3	99.2	-	-	-
112	112.1	101.3	-	-	-
113	99.0	100.6	-	-	-
114	105.1	103.5	-	-	-
115	90.6	85.0	-	-	-
116	103.7	83.3	80.2	84.2	77.4
117	95.1	93.6	81.4	82.7	77.2
118	97.1	89.3	73.6	78.7	77.7
119	99.4	96.0	91.2	87.3	86.1
120	94.2	87.8	81.8	87.5	79.7
Mean	96.59	93.89	81.64	84.09	79.63
SD	6.84	6.67	6.27	3.65	3.75
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
136	83.3	92.8	-	-	-
137	88.0	93.2	-	-	-
138	94.4	100.8	-	-	-
139	88.9	95.9	-	-	-
140	78.6	91.5	-	-	-
141	77.8	89.0	-	-	-
142	99.6	95.5	-	-	-
143	90.9	96.0	-	-	-
144	89.9	101.8	-	-	-
145	73.8	80.6	-	-	-
146	86.3	89.9	91.4	84.8	78.1
147	85.1	90.9	88.7	98.8	83.4
148	85.4	89.0	79.0	99.8	86.0
149	80.3	90.2	84.9	97.7	68.9
150	75.7	87.4	87.1	100.5	84.4
Mean	85.20	92.31	86.22	96.32	80.15
SD	7.16	5.32	4.66	6.53	6.97
N	15	15	5	5	5

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
166	92.5	-	-	-	-
167	89.9	-	-	-	-
168	99.2	-	-	-	-
169	87.8	-	-	-	-
170	76.9	-	-	-	-
171	84.3	-	-	-	-
172	85.5	-	-	-	-
173	89.0	-	-	-	-
174	86.2	-	-	-	-
175	87.4	-	-	-	-
176	83.9	88.4	78.0	90.0	-
177	95.5	92.2	95.0	84.6	-
178	95.4	100.9	94.6	94.3	-
179	84.9	91.7	92.4	89.4	-
180	92.9	86.7	84.2	85.5	-
Mean	88.75	91.99	88.83	88.76	-
SD	5.68	5.49	7.46	3.90	-
N	15	5	5	5	-

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TABLE 4-2 Food Consumption - Individual Data Rat

Sex: Female Relative Food Consumption (g/kg b.w./day)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date				
	TW 1	TW 2	TW 3	TW 4	TW 5
196	72.8	85.2	-	-	-
197	88.1	101.2	-	-	-
198	83.7	100.5	-	-	-
199	86.8	94.3	-	-	-
200	76.7	85.5	-	-	-
201	90.0	93.3	-	-	-
202	86.3	90.3	-	-	-
203	84.2	94.9	-	-	-
204	86.6	98.2	-	-	-
205	79.9	83.8	-	-	-
206	83.7	93.3	88.4	100.0	87.8
207	82.6	87.8	83.1	95.6	84.0
208	91.1	93.7	90.2	96.7	81.6
209	89.6	94.2	87.1	95.8	90.9
210	90.4	87.0	78.1	96.2	84.5
Mean	84.82	92.22	85.38	96.84	85.75
SD	5.22	5.49	4.86	1.80	3.65
N	15	15	5	5	5

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date						
		1 (4 h pa) [a]	2 (24h pa) [a]	8 (4 h pa) [a1]	9 (24h pa) [a]	15 [a2]	15 (4 h pa) [a2]	16 (24h pa) [a2]
Group 1:	Mean	37.36	37.51	37.26	37.31	-	38.25	38.04
Control	SD	0.21	0.37	0.25	0.56	-	0.29	0.38
	N	15	15	15	15	-	15	15
		-	-	-	-	-	-	-
Group 2:	Mean	37.92**	38.54**	37.91**	39.03**	-	38.23	38.91**
30 µg/	SD	0.38	0.27	0.49	0.37	-	0.35	0.46
animal	N	15	15	15	15	-	15	15
BNT162a1	%Diff	1.5	2.8	1.7	4.6	-	0.0	2.3
Group 3:	Mean	37.69*	36.98	37.59	38.05	-	37.62**	38.18
10 µg/	SD	0.30	0.69	0.36	0.33	-	0.56	0.43
animal	N	15	15	15	15	-	15	15
BNT162a1	%Diff	0.9	-1.4	0.9	2.0	-	-1.6	0.4
Group 4:	Mean	37.57	37.76	37.46	38.19**	-	37.43**	37.97
30 µg/	SD	0.48	0.35	0.50	0.49	-	0.38	0.46
animal	N	15	15	15	15	-	15	15
BNT162b1	%Diff	0.6	0.7	0.5	2.4	-	-2.1	-0.2

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a2] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date						
		1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15	15 (4 h pa)	16 (24h pa)
Group 5:	Mean	38.65**	36.70**	38.01**	38.97**	-	38.74*	39.09**
100 µg/	SD	0.58	0.71	0.43	0.36	-	0.58	0.40
animal	N	15	15	15	15	-	15	15
BNT162b1	%Diff	3.5	-2.2	2.0	4.5	-	1.3	2.8
Group 6:	Mean	38.27**	36.59**	37.98**	38.98**	38.60n	-	-
30 µg/	SD	0.32	0.87	0.27	0.20	0.23	-	-
animal	N	15	15	15	15	5	-	-
BNT162c1	%Diff	2.4	-2.5	1.9	4.5	-	-	-
Group 7:	Mean	38.49**	37.45	38.07**	38.94**	-	38.60	39.11**
100 µg/	SD	0.38	0.75	0.38	0.52	-	0.54	0.34
animal	N	15	15	15	15	-	15	15
BNT162b2	%Diff	3.0	-0.2	2.2	4.4	-	0.9	2.8

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01; n - Inappropriate for statistics

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date		
		22 [a]	29 [a]	36 [a1]
Group 1:	Mean	37.40	37.72	36.82
Control	SD	0.55	0.47	0.62
	N	5	5	5
	-	-	-	-
Group 2:	Mean	37.80	38.42	37.42
30 µg/	SD	0.59	0.23	0.68
animal	N	5	5	5
BNT162a1	%Diff	1.1	1.9	1.6
Group 3:	Mean	38.36*	38.58	37.62
10 µg/	SD	0.43	0.64	0.70
animal	N	5	5	5
BNT162a1	%Diff	2.6	2.3	2.2
Group 4:	Mean	38.40*	38.66*	38.24*
30 µg/	SD	0.55	0.54	0.85
animal	N	5	5	5
BNT162b1	%Diff	2.7	2.5	3.9

[a] - Anova & Dunnett: * = $p \leq 0.05$
[a1] - Anova & Dunnett(Rank): * = $p \leq 0.05$

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Male		Day(s) Relative to Start Date		
		22	29	36
Group 5:	Mean	38.38*	38.38	37.46
100 µg/	SD	0.49	0.68	0.86
animal	N	5	5	5
BNT162b1	%Diff	2.6	1.7	1.7
Group 6:	Mean	38.48**	39.00**	-
30 µg/	SD	0.34	0.36	-
animal	N	5	5	-
BNT162c1	%Diff	2.9	3.4	-
Group 7:	Mean	38.44*	38.68*	36.96
100 µg/	SD	0.38	0.44	0.39
animal	N	5	5	5
BNT162b2	%Diff	2.8	2.5	0.4

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

FDA-CBER-2021-5683-0766104

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date						
		1 (4 h pa) [a]	2 (24h pa) [a1]	3 (48h pa) [a]	8 (4 h pa) [a1]	9 (24h pa) [a1]	15 [a]	15 (4 h pa) [a]
Group 1:	Mean	37.37	38.25	-	37.64	38.43	-	38.87
Control	SD	0.30	0.67	-	0.54	0.78	-	0.30
	N	15	15	-	15	15	-	15
		-	-	-	-	-	-	-
Group 2:	Mean	38.30**	38.63	-	38.35**	39.05	-	38.65
30 µg/	SD	0.62	0.38	-	0.37	0.40	-	0.49
animal	N	15	15	-	15	15	-	15
BNT162a1	%Diff	2.5	1.0	-	1.9	1.6	-	-0.5
Group 3:	Mean	38.19**	38.38	-	37.95	38.79	-	38.91
10 µg/	SD	0.52	0.42	-	0.57	0.47	-	0.63
animal	N	15	15	-	15	15	-	15
BNT162a1	%Diff	2.2	0.3	-	0.8	0.9	-	0.1
Group 4:	Mean	37.73	38.47	-	38.15	38.66	-	37.63**
30 µg/	SD	0.53	0.63	-	0.81	0.58	-	0.55
animal	N	15	15	-	15	15	-	15
BNT162b1	%Diff	1.0	0.6	-	1.3	0.6	-	-3.2

[a] - Anova & Dunnett: ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date						
		1 (4 h pa)	2 (24h pa)	3 (48h pa)	8 (4 h pa)	9 (24h pa)	15	15 (4 h pa)
Group 5:	Mean	38.41**	38.35	-	38.22*	38.99	-	39.17
100 µg/	SD	0.43	0.73	-	0.53	0.30	-	0.47
animal	N	15	15	-	15	15	-	15
BNT162b1	%Diff	2.8	0.2	-	1.5	1.4	-	0.8
Group 6:	Mean	38.69**	38.12	39.20n	38.44**	39.03	38.70n	-
30 µg/	SD	0.57	1.16	-	0.64	0.45	0.37	-
animal	N	15	15	1	15	15	5	-
BNT162c1	%Diff	3.6	-0.3	-	2.1	1.6	-	-
Group 7:	Mean	38.51**	39.09**	-	38.35**	39.29**	-	39.13
100 µg/	SD	0.44	0.27	-	0.28	0.38	-	0.43
animal	N	15	15	-	15	15	-	15
BNT162b2	%Diff	3.1	2.2	-	1.9	2.2	-	0.7

Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01; n - Inappropriate for statistics

FDA-CBER-2021-5683-0766106

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date				
		16 (24h pa) [a]	17 [a]	22 [a]	29 [a1]	36 [a1]
Group 1:	Mean	39.01	-	38.84	38.32	38.26
Control	SD	0.41	-	0.71	0.83	1.07
	N	15	-	5	5	5
		-	-	-	-	-
Group 2:	Mean	39.20	-	39.04	38.90	38.76
30 µg/	SD	0.59	-	0.55	0.28	0.91
animal	N	15	-	5	5	5
BNT162a1	%Diff	0.5	-	0.5	1.5	1.3
Group 3:	Mean	39.13	-	39.04	39.06	38.76
10 µg/	SD	0.48	-	0.37	0.49	0.84
animal	N	15	-	5	5	5
BNT162a1	%Diff	0.3	-	0.5	1.9	1.3
Group 4:	Mean	39.04	-	38.92	38.84	38.74
30 µg/	SD	0.56	-	0.36	0.43	0.30
animal	N	15	-	5	5	5
BNT162b1	%Diff	0.1	-	0.2	1.4	1.3

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 5-1 Body Temperature - Summary Rat

Body Temperature (°C)

Sex: Female		Day(s) Relative to Start Date				
		16 (24h pa)	17	22	29	36
Group 5:	Mean	39.43	38.50 n	39.04	39.28	39.06
100 µg/	SD	0.47	-	0.35	0.24	0.34
animal	N	15	1	5	5	5
BNT162b1	%Diff	1.1	-	0.5	2.5	2.1
Group 6:	Mean	-	-	38.90	39.08	-
30 µg/	SD	-	-	0.20	0.34	-
animal	N	-	-	5	5	-
BNT162c1	%Diff	-	-	0.2	2.0	-
Group 7:	Mean	39.51*	-	39.00	39.00	39.18
100 µg/	SD	0.38	-	0.31	0.25	0.15
animal	N	15	-	5	5	5
BNT162b2	%Diff	1.3	-	0.4	1.8	2.4

Anova & Dunnett: * = p ≤ 0.05; n - Inappropriate for statistics

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TABLE 5-1 Body Temperature - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Temperature	2	Male	1 (4 h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	2	Male	2 (24h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	2	Male	8 (4 h pa)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	Body Temperature	2	Male	9 (24h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	2	Male	16 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	3	Male	1 (4 h pa)	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Temperature	3	Male	15 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	4	Male	9 (24h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	4	Male	15 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	3	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	4	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	4	Male	29	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	4	Male	36	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	Body Temperature	5	Male	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	2 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Male	15 (4 h pa)	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	5	Male	16 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	2 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	15	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	7	Male	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	16 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 5-1 Body Temperature - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Temperature	5	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	6	Male	22	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Male	29	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Male	22	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	7	Male	29	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 5-1 Body Temperature - Summary Rat

Comments and Markers

Page	Measurement	Group	Sex	Day	Marker	Comment
	Body Temperature	2	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	2	Female	8 (4 h pa)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	Body Temperature	3	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	4	Female	15 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Female	8 (4 h pa)	*	Anova & Dunnett: * = p ≤ 0.05
	Body Temperature	6	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Female	3 (48h pa)	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	6	Female	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	6	Female	15	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	7	Female	1 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Female	2 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Female	8 (4 h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	7	Female	9 (24h pa)	**	Anova & Dunnett: ** = p ≤ 0.01
	Body Temperature	5	Female	17	n	Anova & Dunnett: n - Inappropriate for statistics
	Body Temperature	7	Female	16 (24h pa)	*	Anova & Dunnett: * = p ≤ 0.05

FDA-CBER-2021-5683-0766111

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
1	37.1	37.1	37.2	36.9	38.4	38.2	-
2	37.3	37.5	37.4	38.0	38.7	38.8	-
3	37.2	37.2	37.3	37.2	38.2	37.6	-
4	37.4	38.2	37.3	37.4	38.7	38.1	-
5	37.4	37.6	37.1	38.1	37.9	38.2	-
6	37.9	37.4	37.3	37.2	38.2	37.7	-
7	37.4	37.2	36.9	36.6	38.3	38.1	-
8	37.7	38.2	37.7	37.4	38.7	38.4	-
9	37.3	37.3	37.3	37.7	38.0	38.5	-
10	37.2	37.0	37.0	37.9	38.3	38.3	-
11	37.1	38.0	36.9	38.0	38.1	37.9	36.6
12	37.3	37.3	37.7	37.4	38.1	37.4	37.1
13	37.4	37.6	37.1	36.5	38.2	37.7	37.6
14	37.4	37.4	37.5	36.5	37.7	37.7	38.0
15	37.3	37.6	37.2	36.8	38.2	38.0	37.7
Mean	37.36	37.51	37.26	37.31	38.25	38.04	37.40
SD	0.21	0.37	0.25	0.56	0.29	0.38	0.55
N	15	15	15	15	15	15	5

FDA-CBER-2021-5683-0766112

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date	
	29	36
1	-	-
2	-	-
3	-	-
4	-	-
5	-	-
6	-	-
7	-	-
8	-	-
9	-	-
10	-	-
11	37.4	36.4
12	37.8	36.5
13	37.1	36.8
14	38.1	36.5
15	38.2	37.9
Mean	37.72	36.82
SD	0.47	0.62
N	5	5

FDA-CBER-2021-5683-0766113

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
31	37.8	38.3	37.5	38.6	38.7	39.1	-
32	37.4	38.4	37.8	39.1	37.9	39.1	-
33	38.2	39.0	38.2	39.1	38.0	39.2	-
34	37.2	38.5	37.4	38.8	37.9	37.8	-
35	38.1	38.3	38.2	38.8	38.5	38.5	-
36	38.1	38.3	37.4	39.2	38.4	39.2	-
37	38.6	39.0	38.7	39.4	38.6	39.2	-
38	38.2	38.6	38.8	39.3	38.2	39.6	-
39	38.2	38.6	38.3	39.5	38.3	39.1	-
40	38.2	38.7	38.1	39.1	38.3	39.0	-
41	38.0	38.3	37.9	38.8	38.5	39.2	38.3
42	37.9	39.0	37.3	39.5	38.1	38.7	37.1
43	37.3	38.2	37.2	38.1	38.6	38.3	37.7
44	37.8	38.4	38.0	38.9	38.1	38.5	38.5
45	37.8	38.5	37.8	39.2	37.4	39.1	37.4
Mean	37.92	38.54	37.91	39.03	38.23	38.91	37.80
SD	0.38	0.27	0.49	0.37	0.35	0.46	0.59
N	15	15	15	15	15	15	5

FDA-CBER-2021-5683-0766114

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date	
	29	36
31	-	-
32	-	-
33	-	-
34	-	-
35	-	-
36	-	-
37	-	-
38	-	-
39	-	-
40	-	-
41	38.5	38.6
42	38.5	37.4
43	38.7	36.9
44	38.3	37.1
45	38.1	37.1
Mean	38.42	37.42
SD	0.23	0.68
N	5	5

FDA-CBER-2021-5683-0766115

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
61	37.7	37.7	37.2	37.8	36.8	38.1	-
62	38.0	36.4	37.7	37.9	37.4	38.4	-
63	37.7	36.1	37.4	37.8	37.0	38.2	-
64	37.6	38.1	37.7	38.6	37.7	38.8	-
65	37.6	38.0	37.3	38.1	37.3	37.8	-
66	37.2	37.3	37.0	37.8	37.4	38.4	-
67	37.4	36.4	37.5	37.7	38.4	37.7	-
68	38.4	36.9	38.4	38.9	38.7	38.2	-
69	37.4	36.3	37.3	38.0	38.0	38.2	-
70	37.4	36.5	37.3	38.0	37.3	38.7	-
71	37.6	37.8	37.6	38.0	37.2	38.7	38.0
72	37.9	36.6	37.9	38.1	37.7	38.5	38.2
73	37.7	36.2	38.0	38.2	38.5	38.0	39.1
74	38.0	37.0	37.8	37.7	37.3	37.2	38.2
75	37.7	37.4	37.8	38.1	37.6	37.8	38.3
Mean	37.69	36.98	37.59	38.05	37.62	38.18	38.36
SD	0.30	0.69	0.36	0.33	0.56	0.43	0.43
N	15	15	15	15	15	15	5

FDA-CBER-2021-5683-0766116

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date	
	29	36
61	-	-
62	-	-
63	-	-
64	-	-
65	-	-
66	-	-
67	-	-
68	-	-
69	-	-
70	-	-
71	38.7	37.3
72	39.2	38.7
73	38.8	37.9
74	37.5	36.9
75	38.7	37.3
Mean	38.58	37.62
SD	0.64	0.70
N	5	5

FDA-CBER-2021-5683-0766117

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
91	38.3	38.5	37.8	38.5	37.9	37.2	-
92	37.4	37.6	37.7	38.3	37.3	38.0	-
93	37.3	38.5	37.0	38.0	37.3	38.0	-
94	36.7	37.7	36.5	38.3	37.0	37.9	-
95	37.4	37.7	37.4	39.0	38.2	37.6	-
96	37.7	37.7	37.2	37.4	36.9	38.0	-
97	38.6	37.9	37.4	38.2	37.5	38.2	-
98	37.8	37.6	37.8	38.5	37.4	38.2	-
99	36.9	37.4	37.3	38.4	37.4	38.2	-
100	37.6	37.8	37.5	38.1	37.4	37.9	-
101	37.7	37.7	38.8	39.0	37.7	39.0	39.3
102	37.7	37.2	37.5	37.2	37.0	37.1	38.3
103	37.4	37.8	37.6	38.1	38.0	38.3	38.4
104	37.2	37.5	37.3	37.8	37.1	37.8	37.8
105	37.8	37.8	37.1	38.1	37.3	38.2	38.2
Mean	37.57	37.76	37.46	38.19	37.43	37.97	38.40
SD	0.48	0.35	0.50	0.49	0.38	0.46	0.55
N	15	15	15	15	15	15	5

FDA-CBER-2021-5683-0766118

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date	
	29	36
91	-	-
92	-	-
93	-	-
94	-	-
95	-	-
96	-	-
97	-	-
98	-	-
99	-	-
100	-	-
101	39.4	39.5
102	38.8	38.7
103	38.3	37.9
104	38.8	37.5
105	38.0	37.6
Mean	38.66	38.24
SD	0.54	0.85
N	5	5

FDA-CBER-2021-5683-0766119

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
121	38.2	38.0	38.2	38.4	38.3	39.4	-
122	38.0	35.7	38.4	39.4	39.4	39.5	-
123	38.0	36.7	37.6	38.6	38.2	39.0	-
124	38.2	36.1	37.6	38.8	37.8	38.6	-
125	39.2	37.4	38.0	39.4	39.7	39.1	-
126	38.5	36.8	38.0	38.7	38.6	39.1	-
127	38.1	38.1	37.7	39.5	39.1	39.2	-
128	39.4	37.2	38.7	39.0	39.3	39.7	-
129	39.3	36.8	37.4	39.2	38.6	39.3	-
130	38.0	36.1	38.0	38.8	38.8	39.4	-
131	39.1	36.4	38.7	38.7	39.1	39.1	38.2
132	38.8	36.5	38.5	39.4	39.2	39.3	37.8
133	39.5	36.1	38.0	39.2	38.5	38.7	38.6
134	39.2	36.1	38.0	39.0	38.8	38.9	39.1
135	38.3	36.5	37.4	38.5	37.7	38.1	38.2
Mean	38.65	36.70	38.01	38.97	38.74	39.09	38.38
SD	0.58	0.71	0.43	0.36	0.58	0.40	0.49
N	15	15	15	15	15	15	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date	
	29	36
121	-	-
122	-	-
123	-	-
124	-	-
125	-	-
126	-	-
127	-	-
128	-	-
129	-	-
130	-	-
131	37.7	38.2
132	37.8	36.6
133	39.1	38.3
134	39.1	37.7
135	38.2	36.5
Mean	38.38	37.46
SD	0.68	0.86
N	5	5

FDA-CBER-2021-5683-0766121

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15	22	29
151	38.1	35.7	37.9	38.8	-	-	-
152	38.6	37.5	37.9	38.7	-	-	-
153	38.2	35.5	38.1	39.0	-	-	-
154	38.1	36.1	37.8	39.0	-	-	-
155	38.2	36.4	37.7	38.7	-	-	-
156	38.1	36.7	37.4	39.0	-	-	-
157	38.2	36.3	38.1	38.8	-	-	-
158	39.1	36.1	38.0	39.4	-	-	-
159	38.2	37.8	38.1	39.0	-	-	-
160	38.0	37.2	38.0	38.8	-	-	-
161	38.5	38.1	38.1	39.2	39.0	38.6	39.1
162	38.1	36.9	38.2	39.0	38.6	38.6	38.6
163	38.2	37.4	38.0	39.1	38.5	38.8	39.5
164	38.6	35.9	38.6	39.2	38.4	38.5	39.1
165	37.8	35.2	37.8	39.0	38.5	37.9	38.7
Mean	38.27	36.59	37.98	38.98	38.60	38.48	39.00
SD	0.32	0.87	0.27	0.20	0.23	0.34	0.36
N	15	15	15	15	5	5	5

FDA-CBER-2021-5683-0766122

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	22
181	38.2	38.7	38.1	39.2	38.5	38.6	-
182	39.1	37.2	39.0	39.4	39.3	39.1	-
183	38.6	37.7	38.1	39.4	37.8	39.4	-
184	38.6	37.3	38.1	39.0	38.5	39.1	-
185	38.8	37.6	38.3	38.1	38.6	38.4	-
186	38.9	36.1	38.6	39.6	39.5	39.5	-
187	38.2	38.3	37.7	39.1	37.8	38.9	-
188	38.5	37.1	38.1	38.1	39.0	39.4	-
189	37.6	38.3	37.4	38.8	38.4	39.2	-
190	38.4	37.8	38.0	38.5	39.0	38.9	-
191	38.6	37.2	38.0	38.4	38.3	39.0	38.0
192	38.4	36.0	37.7	39.1	38.4	39.2	38.6
193	38.1	37.3	37.8	38.5	37.8	39.3	39.0
194	38.4	38.0	38.2	39.7	39.1	39.7	38.3
195	38.9	37.1	38.0	39.2	39.0	38.9	38.3
Mean	38.49	37.45	38.07	38.94	38.60	39.11	38.44
SD	0.38	0.75	0.38	0.52	0.54	0.34	0.38
N	15	15	15	15	15	15	5

FDA-CBER-2021-5683-0766123

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Male Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date	
	29	36
181	-	-
182	-	-
183	-	-
184	-	-
185	-	-
186	-	-
187	-	-
188	-	-
189	-	-
190	-	-
191	38.1	36.6
192	39.3	36.5
193	38.8	37.4
194	38.5	37.1
195	38.7	37.2
Mean	38.68	36.96
SD	0.44	0.39
N	5	5

FDA-CBER-2021-5683-0766124

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
16	37.1	38.4	37.6	39.0	38.8	38.9	-
17	37.2	38.0	37.4	37.7	38.6	38.7	-
18	37.0	37.5	38.0	38.3	38.1	38.1	-
19	37.3	37.3	37.4	36.6	39.2	39.0	-
20	37.3	37.6	37.0	38.2	39.1	38.8	-
21	37.3	37.7	37.3	38.1	38.7	38.7	-
22	37.3	39.4	38.3	39.4	39.0	39.6	-
23	37.7	37.7	38.5	39.4	38.8	39.2	-
24	37.9	38.7	38.3	38.8	38.8	39.1	-
25	37.2	38.6	37.1	38.0	38.8	38.8	-
26	37.4	39.4	37.2	39.0	39.4	39.2	-
27	37.0	37.8	37.0	37.5	38.7	39.1	-
28	37.2	38.2	38.5	39.0	39.0	38.7	-
29	37.7	38.9	37.4	39.0	39.0	39.7	-
30	37.9	38.6	37.6	38.5	39.0	39.5	-
Mean	37.37	38.25	37.64	38.43	38.87	39.01	-
SD	0.30	0.67	0.54	0.78	0.30	0.41	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 1: Control	Day(s) Relative to Start Date		
	22	29	36
16	-	-	-
17	-	-	-
18	-	-	-
19	-	-	-
20	-	-	-
21	-	-	-
22	-	-	-
23	-	-	-
24	-	-	-
25	-	-	-
26	38.7	39.0	39.4
27	37.7	36.9	37.1
28	39.0	38.7	37.7
29	39.5	38.7	37.7
30	39.3	38.3	39.4
Mean	38.84	38.32	38.26
SD	0.71	0.83	1.07
N	5	5	5

FDA-CBER-2021-5683-0766126

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
46	38.8	38.5	38.2	39.0	38.4	38.9	-
47	38.4	38.3	37.7	38.7	39.0	39.7	-
48	37.8	38.5	38.1	38.5	38.0	38.3	-
49	37.4	38.8	38.0	39.2	37.7	39.2	-
50	37.2	38.1	38.3	38.8	38.5	39.1	-
51	38.2	38.6	38.8	39.2	39.0	39.4	-
52	38.9	38.6	38.0	39.1	38.2	38.7	-
53	37.7	38.7	38.6	39.8	38.7	40.2	-
54	38.5	38.6	38.7	38.7	39.6	39.9	-
55	39.4	39.6	38.9	39.7	39.4	39.9	-
56	38.5	38.2	38.4	38.8	38.6	38.9	-
57	38.6	39.1	38.5	39.2	38.5	39.8	-
58	38.6	38.8	38.9	39.6	38.8	39.0	-
59	38.8	38.8	38.2	38.7	38.7	38.5	-
60	37.7	38.2	38.0	38.7	38.7	38.5	-
Mean	38.30	38.63	38.35	39.05	38.65	39.20	-
SD	0.62	0.38	0.37	0.40	0.49	0.59	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 2: 30 µg/ animal BNT162a1	Day(s) Relative to Start Date		
	22	29	36
46	-	-	-
47	-	-	-
48	-	-	-
49	-	-	-
50	-	-	-
51	-	-	-
52	-	-	-
53	-	-	-
54	-	-	-
55	-	-	-
56	39.5	39.0	39.7
57	39.1	38.6	39.2
58	39.4	38.6	37.3
59	39.1	39.1	39.0
60	38.1	39.2	38.6
Mean	39.04	38.90	38.76
SD	0.55	0.28	0.91
N	5	5	5

FDA-CBER-2021-5683-0766128

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
76	38.2	38.2	38.2	38.7	38.7	38.5	-
77	39.1	39.0	37.4	38.5	39.1	39.0	-
78	38.0	38.8	37.4	38.6	38.5	38.5	-
79	38.1	38.0	38.6	39.4	39.1	39.5	-
80	38.0	38.0	37.8	38.6	39.4	39.3	-
81	38.6	38.4	38.0	38.4	39.6	38.7	-
82	37.7	37.7	38.0	38.6	38.0	39.4	-
83	38.9	38.3	37.8	38.6	38.3	39.0	-
84	37.7	38.0	37.7	38.9	38.1	38.8	-
85	39.0	38.9	39.1	39.7	39.6	39.9	-
86	38.2	38.7	37.2	38.4	39.3	39.5	-
87	37.6	37.8	37.3	38.1	37.8	38.3	-
88	37.4	38.5	37.9	38.6	39.4	39.6	-
89	38.0	38.7	39.0	39.6	39.1	39.4	-
90	38.4	38.7	37.9	39.2	39.6	39.5	-
Mean	38.19	38.38	37.95	38.79	38.91	39.13	-
SD	0.52	0.42	0.57	0.47	0.63	0.48	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 3: 10 µg/ animal BNT162a1	Day(s) Relative to Start Date		
	22	29	36
76	-	-	-
77	-	-	-
78	-	-	-
79	-	-	-
80	-	-	-
81	-	-	-
82	-	-	-
83	-	-	-
84	-	-	-
85	-	-	-
86	39.1	39.2	38.8
87	38.4	38.2	37.4
88	39.1	39.2	39.3
89	39.3	39.4	39.6
90	39.3	39.3	38.7
Mean	39.04	39.06	38.76
SD	0.37	0.49	0.84
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
106	37.1	38.1	39.0	39.1	37.2	38.8	-
107	37.5	39.0	39.2	39.2	37.7	39.3	-
108	38.2	37.2	37.5	37.9	37.2	38.7	-
109	37.7	38.5	39.0	39.1	37.6	38.4	-
110	37.9	38.5	38.7	39.3	37.9	39.1	-
111	38.0	38.8	37.2	38.3	37.8	38.3	-
112	39.1	39.9	39.5	39.6	39.0	40.0	-
113	37.7	38.5	37.7	38.6	37.7	39.3	-
114	37.2	38.0	38.8	38.6	38.6	39.8	-
115	38.1	38.0	37.0	39.2	36.9	38.2	-
116	37.4	38.9	38.0	38.4	37.2	39.4	-
117	37.2	37.8	37.2	37.6	37.4	38.6	-
118	37.4	38.6	37.7	38.2	37.6	38.7	-
119	38.2	39.0	37.7	38.7	37.4	39.7	-
120	37.3	38.2	38.0	38.1	37.2	39.3	-
Mean	37.73	38.47	38.15	38.66	37.63	39.04	-
SD	0.53	0.63	0.81	0.58	0.55	0.56	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 4: 30 µg/ animal BNT162b1	Day(s) Relative to Start Date		
	22	29	36
106	-	-	-
107	-	-	-
108	-	-	-
109	-	-	-
110	-	-	-
111	-	-	-
112	-	-	-
113	-	-	-
114	-	-	-
115	-	-	-
116	39.0	39.5	38.8
117	38.6	39.0	38.6
118	38.8	38.4	38.3
119	38.7	38.7	39.0
120	39.5	38.6	39.0
Mean	38.92	38.84	38.74
SD	0.36	0.43	0.30
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
136	39.3	37.1	38.0	38.9	39.2	39.1	-
137	38.4	37.7	38.2	39.2	39.0	39.7	-
138	39.2	39.0	39.5	39.5	39.8	39.9	-
139	38.3	38.5	38.0	38.6	39.4	38.6	-
140	37.9	38.4	37.4	39.0	39.7	39.6	-
141	37.7	37.8	37.5	39.0	39.3	38.8	-
142	38.1	38.7	38.0	38.9	39.5	39.2	-
143	38.3	37.8	38.2	38.9	38.5	39.4	-
144	38.7	39.1	38.4	38.8	38.5	39.9	-
145	38.4	38.9	38.2	39.2	38.2	39.0	-
146	38.3	39.3	38.5	39.1	39.2	39.3	-
147	38.1	37.2	37.8	39.1	39.6	39.8	-
148	38.3	37.7	38.2	38.6	39.0	39.0	-
149	38.4	38.9	39.0	38.5	39.5	40.2	38.5
150	38.7	39.1	38.4	39.5	39.1	39.9	-
Mean	38.41	38.35	38.22	38.99	39.17	39.43	38.50
SD	0.43	0.73	0.53	0.30	0.47	0.47	-
N	15	15	15	15	15	15	1

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 5: 100 µg/ animal BNT162b1	Day(s) Relative to Start Date		
	22	29	36
136	-	-	-
137	-	-	-
138	-	-	-
139	-	-	-
140	-	-	-
141	-	-	-
142	-	-	-
143	-	-	-
144	-	-	-
145	-	-	-
146	38.5	38.9	38.6
147	39.4	39.4	39.2
148	38.9	39.4	39.5
149	39.2	39.5	39.1
150	39.2	39.2	38.9
Mean	39.04	39.28	39.06
SD	0.35	0.24	0.34
N	5	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	3 (48h pa)	8 (4 h pa)	9 (24h pa)	15	22
166	39.5	39.1	-	39.0	39.2	-	-
167	38.1	35.7	-	37.7	38.9	-	-
168	38.0	38.8	-	38.2	38.7	-	-
169	39.6	38.5	-	38.0	38.9	-	-
170	38.6	37.1	-	37.7	38.7	-	-
171	39.6	40.0	39.2	39.6	39.4	-	-
172	38.0	38.0	-	39.6	39.8	-	-
173	38.8	38.7	-	39.2	39.4	-	-
174	38.7	38.5	-	38.6	38.7	-	-
175	38.2	36.7	-	38.0	38.5	-	-
176	38.7	38.7	-	38.3	39.2	38.8	38.8
177	39.1	39.1	-	37.8	39.5	38.7	39.0
178	39.0	37.1	-	38.3	38.1	39.1	38.8
179	38.1	36.9	-	38.0	39.1	38.8	39.2
180	38.4	38.9	-	38.6	39.4	38.1	38.7
Mean	38.69	38.12	39.20	38.44	39.03	38.70	38.90
SD	0.57	1.16	-	0.64	0.45	0.37	0.20
N	15	15	1	15	15	5	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 6: 30 µg/ animal BNT162c1	Day(s) Relative to Start Date
	29
166	-
167	-
168	-
169	-
170	-
171	-
172	-
173	-
174	-
175	-
176	39.2
177	39.1
178	39.4
179	39.2
180	38.5
Mean	39.08
SD	0.34
N	5

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date						
	1 (4 h pa)	2 (24h pa)	8 (4 h pa)	9 (24h pa)	15 (4 h pa)	16 (24h pa)	17
196	39.0	39.3	38.2	39.4	39.0	39.5	-
197	37.7	39.0	38.2	39.1	39.2	38.9	-
198	38.3	38.6	38.7	39.2	38.3	39.4	-
199	38.8	38.8	38.0	39.2	39.5	39.5	-
200	39.0	39.5	38.8	39.6	39.6	39.9	-
201	38.2	39.1	38.1	39.7	38.3	39.6	-
202	38.0	39.3	38.5	39.6	39.2	39.9	-
203	38.5	39.4	38.2	39.0	38.8	39.0	-
204	38.6	39.0	38.5	39.1	39.7	38.9	-
205	38.9	39.1	38.8	39.6	39.5	39.9	-
206	38.5	39.2	38.1	39.6	39.1	39.9	-
207	38.5	38.8	38.6	39.1	39.0	39.9	-
208	37.8	38.7	38.0	38.2	39.2	39.1	-
209	39.0	39.1	38.4	39.4	39.6	39.7	-
210	38.9	39.4	38.2	39.6	39.0	39.6	-
Mean	38.51	39.09	38.35	39.29	39.13	39.51	-
SD	0.44	0.27	0.28	0.38	0.43	0.38	-
N	15	15	15	15	15	15	-

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TABLE 5-2 Body Temperature - Individual Data Rat

Sex: Female Body Temperature (°C)

Group 7: 100 µg/ animal BNT162b2	Day(s) Relative to Start Date		
	22	29	36
196	-	-	-
197	-	-	-
198	-	-	-
199	-	-	-
200	-	-	-
201	-	-	-
202	-	-	-
203	-	-	-
204	-	-	-
205	-	-	-
206	38.8	39.3	39.2
207	39.4	39.2	39.2
208	39.1	38.7	39.0
209	39.1	38.8	39.4
210	38.6	39.0	39.1
Mean	39.00	39.00	39.18
SD	0.31	0.25	0.15
N	5	5	5

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a1]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a2]
Group 1: Control	Mean	8.60	7.270	9.367	4.21	306.96	998.5	41.92
	SD	0.24	0.365	2.087	0.58	36.75	129.0	1.21
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.43	7.218	11.746	1.04**	74.85**	1021.7	40.58
	SD	0.25	0.260	2.519	0.22	14.71	131.1	1.44
	N	10	10	10	10	10	10	10
	%Diff	-2.0	-0.7	25.4	-75.3	-75.6	2.3	-3.2
Group 3: 10 µg/ animal BNT162a1	Mean	8.99*	7.754**	10.574	1.51**	116.28**	1118.6	42.77
	SD	0.42	0.371	1.841	0.34	23.50	154.1	2.03
	N	10	10	10	10	10	10	10
	%Diff	4.5	6.7	12.9	-64.1	-62.1	12.0	2.0
Group 4: 30 µg/ animal BNT162b1	Mean	8.21*	7.126	10.001	2.40	171.12**	1001.6	40.39*
	SD	0.17	0.198	2.166	0.41	28.57	126.9	0.69
	N	10	10	10	10	10	10	10
	%Diff	-4.5	-2.0	6.8	-43.0	-44.3	0.3	-3.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): * = $p \leq 0.05$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.93*	7.784**	10.911	1.45**	112.54**	1051.6	42.53
100 µg/	SD	0.23	0.249	2.388	0.35	26.19	148.2	1.17
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	3.8	7.1	16.5	-65.6	-63.3	5.3	1.5
Group 6:	Mean	8.95*	7.796**	12.886**	0.99**	77.06**	1099.3	42.66
30 µg/	SD	0.34	0.323	2.098	0.28	20.59	147.4	1.31
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	4.1	7.2	37.6	-76.5	-74.9	10.1	1.8
Group 7:	Mean	9.11**	7.848**	12.834**	1.08**	85.52**	948.9	42.88
100 µg/	SD	0.21	0.182	1.431	0.23	16.53	164.8	0.87
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	5.9	8.0	37.0	-74.3	-72.1	-5.0	2.3

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.75 n	7.708 n	20.115 n	2.49 n	192.67 n	708.8 n	41.46 n
	SD	0.37	0.319	4.492	0.50	36.61	100.9	1.90
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a1]	Reti (x10E3/µL) [a1]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	9.14	7.956	9.090	2.96	234.60	1089.2	45.03
	SD	0.25	0.232	2.418	0.37	25.66	199.5	1.21
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.67**	7.723	16.280**	2.26**	174.83**	804.7**	42.43**
	SD	0.31	0.229	3.632	0.46	33.86	148.6	1.50
	N	10	10	10	10	10	10	10
	%Diff	-5.1	-2.9	79.1	-23.6	-25.5	-26.1	-5.8
Group 3: 10 µg/ animal BNT162a1	Mean	8.69**	7.844	14.759**	2.43	190.39*	805.1**	41.10**
	SD	0.31	0.403	2.207	0.39	29.73	169.4	1.40
	N	10	10	10	10	10	10	10
	%Diff	-4.9	-1.4	62.4	-17.9	-18.8	-26.1	-8.7
Group 4: 30 µg/ animal BNT162b1	Mean	8.62**	7.751	14.612**	2.46	188.61*	930.6	42.66**
	SD	0.23	0.285	3.826	0.30	20.68	167.8	1.27
	N	10	10	10	10	10	10	10
	%Diff	-5.7	-2.6	60.7	-16.9	-19.6	-14.6	-5.3

[a] - Anova & Dunnett: ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.14**	7.511	16.564**	3.00	223.29	817.2**	38.79**
100 µg/	SD	0.34	0.430	4.442	0.85	59.50	145.9	1.80
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-10.9	-5.6	82.2	1.4	-4.8	-25.0	-13.9
Group 7:	Mean	8.31**	7.670	19.876**	2.27**	172.94**	771.4**	39.65**
100 µg/	SD	0.33	0.307	5.114	0.41	28.95	121.1	1.55
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-9.1	-3.6	118.7	-23.3	-26.3	-29.2	-11.9

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.80 n	8.456 n	6.900 n	2.40 n	202.06 n	977.4 n	42.62 n
	SD	0.16	0.201	1.457	0.29	27.22	117.6	0.99
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	8.96	8.524	10.126	2.80	236.12	988.4	44.22
	SD	0.46	0.626	2.715	0.62	42.05	160.5	1.79
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	9.00	8.582	9.254	3.04	261.06	1106.4	44.34
	SD	0.20	0.134	1.545	0.34	28.05	64.9	0.67
	N	5	5	5	5	5	5	5
	%Diff	0.4	0.7	-8.6	8.6	10.6	11.9	0.3
Group 3: 10 µg/ animal BNT162a1	Mean	9.04	8.680	9.280	2.56	222.06	1040.0	44.26
	SD	0.45	0.487	2.388	0.40	26.58	185.1	1.97
	N	5	5	5	5	5	5	5
	%Diff	0.9	1.8	-8.4	-8.6	-6.0	5.2	0.1
Group 4: 30 µg/ animal BNT162b1	Mean	8.56	8.338	8.066	2.66	222.08	942.0	42.52
	SD	0.28	0.463	2.376	0.56	39.64	126.0	1.73
	N	5	5	5	5	5	5	5
	%Diff	-4.5	-2.2	-20.3	-5.0	-5.9	-4.7	-3.8

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.86	8.668	9.048	2.32	201.20	921.4	43.56
100 µg/	SD	0.26	0.237	1.157	0.40	40.75	76.2	1.71
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.1	1.7	-10.6	-17.1	-14.8	-6.8	-1.5
Group 7:	Mean	9.08	8.884	10.370	2.40	211.78	1027.0	44.56
100 µg/	SD	0.28	0.351	2.679	0.45	38.99	159.6	1.66
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	1.3	4.2	2.4	-14.3	-10.3	3.9	0.8

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	15.93	78.39	3.10	1.31	0.98	0.28
	SD	2.78	3.54	0.58	0.39	0.39	0.08
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	29.05	60.74	3.42	1.04	5.46	0.33
	SD	3.79	5.51	0.82	0.34	2.17	0.08
	N	10	10	10	10	10	10
	%Diff	82.4	-22.5	10.3	-20.6	457.1	17.9
Group 3: 10 µg/ animal BNT162a1	Mean	13.58	79.92	2.80	1.14	2.11	0.44
	SD	3.45	4.56	0.62	0.41	0.69	0.10
	N	10	10	10	10	10	10
	%Diff	-14.8	2.0	-9.7	-13.0	115.3	57.1
Group 4: 30 µg/ animal BNT162b1	Mean	14.78	79.57	2.57	1.32	1.43	0.33
	SD	3.37	3.61	0.48	0.60	0.52	0.07
	N	10	10	10	10	10	10
	%Diff	-7.2	1.5	-17.1	0.8	45.9	17.9

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	12.08	82.40	1.93	1.10	2.11	0.39
100 µg/	SD	1.79	2.95	0.53	0.37	1.03	0.12
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	-24.2	5.1	-37.7	-16.0	115.3	39.3
Group 6:	Mean	19.64	72.80	3.18	0.75	3.17	0.45
30 µg/	SD	2.52	3.68	1.07	0.24	1.76	0.10
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	23.3	-7.1	2.6	-42.7	223.5	60.7
Group 7:	Mean	15.79	77.95	2.15	0.86	2.76	0.49
100 µg/	SD	6.43	7.77	0.61	0.46	0.75	0.07
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	-0.9	-0.6	-30.6	-34.4	181.6	75.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	44.37	44.33	3.18	0.48	7.18	0.47
	SD	7.23	8.32	1.06	0.18	2.61	0.22
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	16.11	77.96	3.38	1.27	0.95	0.32
	SD	6.39	6.57	0.63	0.34	0.28	0.09
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	47.63	41.20	3.47	0.61	6.73	0.37
	SD	4.39	4.79	0.60	0.17	3.16	0.13
	N	10	10	10	10	10	10
	%Diff	195.7	-47.2	2.7	-52.0	608.4	15.6
Group 3: 10 µg/ animal BNT162a1	Mean	36.56	54.82	4.18	0.75	3.25	0.46
	SD	5.18	4.57	1.32	0.31	1.06	0.08
	N	10	10	10	10	10	10
	%Diff	126.9	-29.7	23.7	-40.9	242.1	43.8
Group 4: 30 µg/ animal BNT162b1	Mean	40.64	51.38	4.35	1.64	1.61	0.41
	SD	6.72	6.71	1.39	0.36	0.32	0.12
	N	10	10	10	10	10	10
	%Diff	152.3	-34.1	28.7	29.1	69.5	28.1

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	46.94	43.82	3.34	2.21	3.32	0.37
100 µg/	SD	6.74	7.90	0.94	0.64	1.32	0.07
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	191.4	-43.8	-1.2	74.0	249.5	15.6
Group 7:	Mean	51.91	39.18	2.53	2.83	3.21	0.34
100 µg/	SD	3.40	4.27	0.98	0.71	1.46	0.13
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	222.2	-49.7	-25.1	122.8	237.9	6.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	21.10	73.18	3.14	1.54	0.82	0.22
	SD	2.21	2.59	0.56	0.17	0.19	0.08
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	17.54	76.02	3.32	1.78	1.08	0.28
	SD	2.88	3.69	0.80	0.63	0.25	0.04
	N	5	5	5	5	5	5
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	15.26	77.78	3.74	1.48	1.46	0.30
	SD	2.29	1.62	0.77	0.48	0.44	0.10
	N	5	5	5	5	5	5
	%Diff	-13.0	2.3	12.7	-16.9	35.2	7.1
Group 3: 10 µg/ animal BNT162a1	Mean	15.74	78.58	2.98	1.54	0.92	0.20
	SD	3.35	4.11	0.89	0.54	0.19	0.07
	N	5	5	5	5	5	5
	%Diff	-10.3	3.4	-10.2	-13.5	-14.8	-28.6
Group 4: 30 µg/ animal BNT162b1	Mean	19.94	73.28	3.54	2.02	1.00	0.26
	SD	5.77	5.50	0.86	0.34	0.29	0.05
	N	5	5	5	5	5	5
	%Diff	13.7	-3.6	6.6	13.5	-7.4	-7.1

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	19.86	74.82	2.52	1.68	0.86	0.24
100 µg/	SD	3.93	4.17	0.39	0.70	0.21	0.11
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	13.2	-1.6	-24.1	-5.6	-20.4	-14.3
Group 7:	Mean	17.94	75.84	3.10	1.76	1.10	0.28
100 µg/	SD	6.72	7.21	0.84	0.57	0.44	0.04
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	2.3	-0.2	-6.6	-1.1	1.9	0.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a1]
Group 1: Control	Mean	1.499	7.338	0.292	0.121	0.089	0.026
	SD	0.458	1.608	0.097	0.037	0.026	0.012
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	3.430**	7.087	0.406	0.121	0.663**	0.038
	SD	0.888	1.507	0.144	0.051	0.305	0.018
	N	10	10	10	10	10	10
	%Diff	128.8	-3.4	39.0	0.0	644.9	46.2
Group 3: 10 µg/ animal BNT162a1	Mean	1.414	8.479	0.296	0.119	0.219**	0.047*
	SD	0.355	1.682	0.080	0.041	0.073	0.018
	N	10	10	10	10	10	10
	%Diff	-5.7	15.5	1.4	-1.7	146.1	80.8
Group 4: 30 µg/ animal BNT162b1	Mean	1.464	7.976	0.255	0.124	0.146	0.035
	SD	0.407	1.830	0.067	0.042	0.079	0.014
	N	10	10	10	10	10	10
	%Diff	-2.3	8.7	-12.7	2.5	64.0	34.6

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.317	8.996	0.209	0.119	0.224**	0.042
100 µg/	SD	0.340	2.006	0.076	0.055	0.097	0.019
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	-12.1	22.6	-28.4	-1.7	151.7	61.5
Group 6:	Mean	2.524**	9.393*	0.405	0.097	0.410**	0.060**
30 µg/	SD	0.478	1.671	0.152	0.029	0.210	0.020
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	68.4	28.0	38.7	-19.8	360.7	130.8
Group 7:	Mean	1.998	10.039**	0.273	0.110	0.352**	0.065**
100 µg/	SD	0.755	1.733	0.082	0.059	0.092	0.014
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	33.3	36.8	-6.5	-9.1	295.5	150.0

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.793 n	9.110 n	0.632 n	0.094 n	1.384 n	0.102 n
	SD	1.767	3.446	0.232	0.037	0.455	0.078
	N	10	10	10	10	10	10
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a1]	Eos (x10E3/µL) [a2]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	1.458	7.094	0.308	0.109	0.088	0.030
	SD	0.707	2.057	0.102	0.014	0.051	0.014
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	7.736**	6.645	0.569*	0.101	1.167**	0.063**
	SD	1.803	1.466	0.184	0.036	0.672	0.029
	N	10	10	10	10	10	10
	%Diff	430.6	-6.3	84.7	-7.3	1226.1	110.0
Group 3: 10 µg/ animal BNT162a1	Mean	5.353**	8.116	0.627**	0.106	0.489**	0.069**
	SD	0.805	1.525	0.241	0.030	0.197	0.017
	N	10	10	10	10	10	10
	%Diff	267.1	14.4	103.6	-2.8	455.7	130.0
Group 4: 30 µg/ animal BNT162b1	Mean	5.893**	7.564	0.623**	0.231**	0.237**	0.060**
	SD	1.610	2.424	0.227	0.049	0.088	0.034
	N	10	10	10	10	10	10
	%Diff	304.2	6.6	102.3	111.9	169.3	100.0

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a2] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	7.980**	7.021	0.548*	0.360**	0.594**	0.063**
100 µg/	SD	3.197	1.113	0.184	0.119	0.453	0.025
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	447.3	-1.0	77.9	230.3	575.0	110.0
Group 7:	Mean	10.291**	7.752	0.502	0.566**	0.691**	0.074**
100 µg/	SD	2.545	2.029	0.230	0.199	0.468	0.040
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	605.8	9.3	63.0	419.3	685.2	146.7

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766159

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.470 n	5.034 n	0.216 n	0.106 n	0.060 n	0.016 n
	SD	0.420	0.984	0.062	0.023	0.016	0.009
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766160

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a1]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	1.806	7.638	0.352	0.194	0.106	0.028
	SD	0.724	1.735	0.185	0.116	0.027	0.015
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.404	7.194	0.350	0.138	0.138	0.028
	SD	0.268	1.173	0.119	0.055	0.056	0.008
	N	5	5	5	5	5	5
	%Diff	-22.3	-5.8	-0.6	-28.9	30.2	0.0
Group 3: 10 µg/ animal BNT162a1	Mean	1.410	7.358	0.268	0.134	0.090	0.018
	SD	0.196	2.272	0.057	0.030	0.041	0.013
	N	5	5	5	5	5	5
	%Diff	-21.9	-3.7	-23.9	-30.9	-15.1	-35.7
Group 4: 30 µg/ animal BNT162b1	Mean	1.530	5.984	0.286	0.160	0.082	0.020
	SD	0.362	2.049	0.113	0.056	0.033	0.010
	N	5	5	5	5	5	5
	%Diff	-15.3	-21.7	-18.8	-17.5	-22.6	-28.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0766161

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.798	6.768	0.224	0.158	0.076	0.022
100 µg/	SD	0.458	0.935	0.013	0.077	0.025	0.013
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-0.4	-11.4	-36.4	-18.6	-28.3	-21.4
Group 7:	Mean	1.830	7.906	0.310	0.180	0.114	0.030
100 µg/	SD	0.623	2.412	0.069	0.080	0.053	0.016
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	1.3	3.5	-11.9	-7.2	7.5	7.1

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0766162

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 1: Control	Mean	57.74	1.184	20.490
	SD	2.12	0.042	0.150
	N	10	10	10
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	56.24	1.167	20.782*
	SD	1.48	0.028	0.244
	N	10	10	10
	%Diff	-2.6	-1.4	1.4
Group 3: 10 µg/ animal BNT162a1	Mean	55.19**	1.161	21.034**
	SD	1.16	0.028	0.286
	N	10	10	10
	%Diff	-4.4	-1.9	2.7
Group 4: 30 µg/ animal BNT162b1	Mean	56.73	1.154	20.362
	SD	1.55	0.025	0.229
	N	10	10	10
	%Diff	-1.7	-2.5	-0.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766163

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	54.63**	1.149	21.039**
	SD	0.93	0.025	0.261
	N	10	10	10
	%Diff	-5.4	-3.0	2.7
Group 6: 30 µg/ animal BNT162c1	Mean	54.75**	1.150	20.990**
	SD	1.44	0.026	0.256
	N	10	10	10
	%Diff	-5.2	-2.9	2.4
Group 7: 100 µg/ animal BNT162b2	Mean	54.68**	1.162	21.252**
	SD	1.38	0.023	0.266
	N	10	10	10
	%Diff	-5.3	-1.9	3.7

[a] - Anova & Dunnett: ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766164

090177e194f4cf37\Approved\Approved On: 18-Sep-2020 13:38 (GMT)

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6:	Mean	9.91 n	18.25 n	298.20 n	53.80 n	1.133 n	21.070 n
30 µg/	SD	0.39	0.78	18.63	1.59	0.021	0.364
animal	N	10	10	10	10	10	10
BNT162c1		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766165

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a2]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 1: Control	Mean	9.57	15.32	106.12	56.61	1.151	20.319
	SD	0.22	1.79	9.55	1.67	0.029	0.270
	N	9	9	9	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.49	17.70**	309.10**	54.96*	1.122	20.403
	SD	0.60	1.40	23.06	1.03	0.017	0.253
	N	10	10	10	10	10	10
	%Diff	-0.8	15.5	191.3	-2.9	-2.5	0.4
Group 3: 10 µg/ animal BNT162a1	Mean	9.70	18.11**	271.00**	52.48**	1.110**	21.153**
	SD	0.37	1.31	22.32	1.47	0.028	0.239
	N	9	9	9	10	10	10
	%Diff	1.4	18.2	155.4	-7.3	-3.6	4.1
Group 4: 30 µg/ animal BNT162b1	Mean	9.56	14.59	271.40**	55.07*	1.113**	20.217
	SD	0.33	0.54	22.57	0.97	0.025	0.305
	N	10	10	10	10	10	10
	%Diff	-0.1	-4.8	155.7	-2.7	-3.3	-0.5

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a2] - Anova & Dunnett(Log): ** = p ≤ 0.01

FDA-CBER-2021-5683-0766166

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	9.33	16.82	310.00**	51.69**	1.085**	20.998**
100 µg/	SD	0.51	1.17	11.81	1.20	0.022	0.336
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	-2.5	9.8	192.1	-8.7	-5.7	3.3
Group 7:	Mean	9.38	17.49*	323.90**	51.72**	1.082**	20.963**
100 µg/	SD	0.45	1.22	27.56	1.43	0.029	0.209
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	-2.0	14.1	205.2	-8.6	-6.0	3.2

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766167

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6:	Mean	9.76 n	14.58 n	140.80 n	50.42 n	1.038 n	20.628 n
30 µg/	SD	0.47	1.03	55.98	0.61	0.025	0.297
animal	N	5	5	5	5	5	5
BNT162c1		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766168

090177e194f4cf37\Approved\Approved On: 18-Sep-2020 13:38 (GMT)

TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a1]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 1: Control	Mean	9.42	15.74	164.34	52.00	1.054	20.280
	SD	0.32	0.90	75.46	1.82	0.034	0.184
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.94	15.78	95.52	51.68	1.052	20.318
	SD	0.38	0.70	7.40	1.08	0.029	0.201
	N	5	5	5	5	5	5
	%Diff	5.5	0.3	-41.9	-0.6	-0.2	0.2
Group 3: 10 µg/ animal BNT162a1	Mean	9.70	15.64	127.80	51.00	1.040	20.378
	SD	0.20	1.23	71.17	1.04	0.020	0.275
	N	5	5	5	5	5	5
	%Diff	3.0	-0.6	-22.2	-1.9	-1.3	0.5
Group 4: 30 µg/ animal BNT162b1	Mean	9.88	15.22	102.90	51.04	1.028	20.106
	SD	0.18	0.24	10.75	1.65	0.029	0.322
	N	5	5	5	5	5	5
	%Diff	4.9	-3.3	-37.4	-1.8	-2.5	-0.9

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0766169

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	9.60	16.46	132.82	50.22	1.020	20.332
100 µg/	SD	0.37	2.24	72.39	0.80	0.007	0.170
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	1.9	4.6	-19.2	-3.4	-3.2	0.3
Group 7:	Mean	9.60	15.90	103.76	50.16	1.024	20.408
100 µg/	SD	0.50	1.55	15.93	0.74	0.023	0.294
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	1.9	1.0	-36.9	-3.5	-2.8	0.6

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0766170

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a1]
Group 1: Control	Mean	7.91	0.790	71.43	12.48	20.69
	SD	0.79	0.108	10.12	0.51	1.31
	N	10	10	10	10	10
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	8.25	0.840	89.37**	13.25**	22.78**
	SD	0.63	0.092	4.39	0.32	1.18
	N	10	10	10	10	10
	%Diff	4.3	6.3	25.1	6.2	10.1
Group 3: 10 µg/ animal BNT162a1	Mean	7.43	0.824	83.89**	12.06	23.49**
	SD	0.76	0.089	6.30	0.48	0.91
	N	10	10	10	10	10
	%Diff	-6.1	4.3	17.4	-3.4	13.5
Group 4: 30 µg/ animal BNT162b1	Mean	8.15	0.814	75.39	12.88	21.21
	SD	0.61	0.099	7.01	0.49	1.15
	N	10	10	10	10	10
	%Diff	3.0	3.0	5.5	3.2	2.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766171

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	7.78	0.818	81.43*	12.14	23.38**
100 µg/	SD	0.53	0.115	8.09	0.36	1.41
animal	N	10	10	10	10	10
BNT162b1	%Diff	-1.6	3.5	14.0	-2.7	13.0
Group 6:	Mean	7.98	0.876	88.08**	12.21	23.58**
30 µg/	SD	0.71	0.126	8.19	0.33	0.39
animal	N	10	10	10	10	10
BNT162c1	%Diff	0.9	10.9	23.3	-2.2	14.0
Group 7:	Mean	8.48	0.803	89.07**	12.03	23.96**
100 µg/	SD	0.47	0.119	8.48	0.32	1.49
animal	N	10	10	10	10	10
BNT162b2	%Diff	7.2	1.6	24.7	-3.6	15.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766172

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.55 n	0.673 n	94.97 n	13.32 n	22.61 n
	SD	1.01	0.110	6.21	0.42	1.39
	N	10	10	10	10	10
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766173

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a1]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	10.91	1.180	56.59	15.17	18.09
	SD	0.88	0.190	2.67	0.74	0.99
	N	10	10	10	10	10
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	11.79	0.941**	70.88**	16.27**	19.73**
	SD	0.90	0.157	6.33	0.54	0.85
	N	10	10	10	10	10
	%Diff	8.1	-20.3	25.3	7.3	9.1
Group 3: 10 µg/ animal BNT162a1	Mean	8.68**	0.690**	84.87**	13.32**	21.21**
	SD	0.81	0.096	6.09	0.62	1.16
	N	10	10	10	10	10
	%Diff	-20.4	-41.5	50.0	-12.2	17.2
Group 4: 30 µg/ animal BNT162b1	Mean	11.55	1.072	61.40*	16.52**	18.64
	SD	0.83	0.188	2.91	0.76	0.82
	N	10	10	10	10	10
	%Diff	5.9	-9.2	8.5	8.9	3.0

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766174

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	9.04**	0.733**	83.22**	13.32**	21.61**
100 µg/	SD	0.69	0.094	5.76	0.66	0.90
animal	N	10	10	10	10	10
BNT162b1	%Diff	-17.1	-37.9	47.1	-12.2	19.5
Group 7:	Mean	9.36**	0.723**	82.52**	13.35**	21.48**
100 µg/	SD	0.66	0.125	3.31	0.59	0.99
animal	N	10	10	10	10	10
BNT162b2	%Diff	-14.2	-38.7	45.8	-12.0	18.7

[a] - Anova & Dunnett: ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766175

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	7.94 n	0.778 n	70.16 n	13.04 n	20.22 n
	SD	0.48	0.131	6.56	0.44	1.10
	N	5	5	5	5	5
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766176

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	8.86	0.866	68.38	11.50	18.90
	SD	0.86	0.106	2.85	0.69	0.85
	N	5	5	5	5	5
	-					
Group 2: 30 µg/ animal BNT162a1	Mean	8.14	0.902	67.70	13.54**	19.56
	SD	0.43	0.072	4.18	0.36	1.14
	N	5	5	5	5	5
	%Diff	-8.1	4.2	-1.0	17.7	3.5
Group 3: 10 µg/ animal BNT162a1	Mean	8.00	0.830	70.42	13.66**	20.34
	SD	0.51	0.112	9.60	0.34	1.02
	N	5	5	5	5	5
	%Diff	-9.7	-4.2	3.0	18.8	7.6
Group 4: 30 µg/ animal BNT162b1	Mean	8.44	0.786	69.08	13.44**	19.62
	SD	0.89	0.083	7.39	0.57	1.09
	N	5	5	5	5	5
	%Diff	-4.7	-9.2	1.0	16.9	3.8

[a] - Anova & Dunnett: ** = p ≤ 0.01

FDA-CBER-2021-5683-0766177

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	8.46	0.774	73.32	13.34 **	19.50
100 µg/	SD	1.00	0.054	8.40	0.42	1.54
animal	N	5	5	5	5	5
BNT162b1	%Diff	-4.5	-10.6	7.2	16.0	3.2
Group 7:	Mean	8.16	0.842	69.26	13.26 **	19.80
100 µg/	SD	0.25	0.143	7.23	0.53	1.15
animal	N	5	5	5	5	5
BNT162b2	%Diff	-7.9	-2.8	1.3	15.3	4.8

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a1]	Reti (%) [a]	Reti (x10E3/µL) [a1]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	8.87	7.654	8.417	2.56	195.69	975.1	41.87
	SD	0.46	0.344	3.256	0.47	33.93	150.4	2.45
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.57	7.295	12.893**	0.97**	69.75**	753.6*	40.41
	SD	0.36	0.334	1.660	0.36	23.24	133.3	1.69
	N	10	10	10	10	10	10	10
	%Diff	-3.4	-4.7	53.2	-62.1	-64.4	-22.7	-3.5
Group 3: 10 µg/ animal BNT162a1	Mean	9.12	7.807	8.719	1.23**	94.88**	1068.3	42.23
	SD	0.36	0.409	2.464	0.35	23.30	242.8	1.90
	N	10	10	10	10	10	10	10
	%Diff	2.8	2.0	3.6	-52.0	-51.5	9.6	0.9
Group 4: 30 µg/ animal BNT162b1	Mean	8.70	7.506	8.311	1.92**	143.85*	985.7	41.39
	SD	0.33	0.474	1.844	0.57	44.93	128.7	1.79
	N	10	10	10	10	10	10	10
	%Diff	-1.9	-1.9	-1.3	-25.0	-26.5	1.1	-1.1

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.62	7.589	9.049	1.47**	112.33**	1048.6	40.49
100 µg/	SD	0.32	0.262	1.822	0.28	20.92	125.9	1.54
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-2.8	-0.8	7.5	-42.6	-42.6	7.5	-3.3
Group 6:	Mean	8.78	7.576	10.029	1.05**	79.63**	1000.2	40.31
30 µg/	SD	0.36	0.339	2.855	0.18	12.83	145.2	1.49
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-1.0	-1.0	19.2	-59.0	-59.3	2.6	-3.7
Group 7:	Mean	8.74	7.578	10.395	1.34**	101.31**	1016.5	40.15
100 µg/	SD	0.35	0.440	2.908	0.33	28.82	116.2	1.80
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-1.5	-1.0	23.5	-47.7	-48.2	4.2	-4.1

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.43 n	7.419 n	15.267 n	2.53 n	184.44 n	570.4 n	38.86 n
	SD	0.33	0.508	2.493	0.73	44.08	145.4	1.55
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	9.08	7.892	7.106	2.56	200.95	1068.1	43.45
	SD	0.36	0.213	2.414	0.53	38.85	140.4	1.83
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.66	7.546	14.500**	2.64	199.77	622.9**	41.74
	SD	0.34	0.340	4.114	0.69	50.73	155.2	1.92
	N	10	10	10	10	10	10	10
	%Diff	-4.6	-4.4	104.1	3.1	-0.6	-41.7	-3.9
Group 3: 10 µg/ animal BNT162a1	Mean	8.38**	7.465*	11.016*	3.04	225.54	698.1**	39.24**
	SD	0.32	0.298	2.490	0.92	66.10	166.4	1.56
	N	10	10	10	10	10	10	10
	%Diff	-7.7	-5.4	55.0	18.8	12.2	-34.6	-9.7
Group 4: 30 µg/ animal BNT162b1	Mean	8.13**	7.248**	12.744**	2.89	209.89	876.8*	39.50**
	SD	0.34	0.296	3.637	0.60	38.31	117.1	1.44
	N	10	10	10	10	10	10	10
	%Diff	-10.5	-8.2	79.3	12.9	4.4	-17.9	-9.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	7.85**	7.145**	14.405**	3.18	226.66	702.2**	37.06**
100 µg/	SD	0.50	0.355	2.642	0.70	43.09	116.6	2.38
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-13.5	-9.5	102.7	24.2	12.8	-34.3	-14.7
Group 7:	Mean	7.93**	7.115**	14.997**	2.78	197.95	704.4**	37.59**
100 µg/	SD	0.35	0.288	3.215	0.58	36.41	148.3	1.81
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-12.7	-9.8	111.0	8.6	-1.5	-34.1	-13.5

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.84 n	8.142 n	5.514 n	3.06 n	248.30 n	1025.8 n	42.12 n
	SD	0.18	0.352	1.521	0.60	42.44	137.3	1.12
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 1: Control	Mean	8.80	8.176	6.084	3.20	259.88	949.8	42.50
	SD	0.31	0.238	1.403	0.76	55.32	265.6	1.58
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	8.66	7.910	7.622	3.00	236.40	940.4	42.34
	SD	0.40	0.407	2.997	1.10	74.87	136.3	1.89
	N	5	5	5	5	5	5	5
	%Diff	-1.6	-3.3	25.3	-6.3	-9.0	-1.0	-0.4
Group 3: 10 µg/ animal BNT162a1	Mean	9.04	8.312	7.012	2.28	189.54	992.8	43.64
	SD	0.24	0.312	2.164	0.43	40.57	194.6	0.94
	N	5	5	5	5	5	5	5
	%Diff	2.7	1.7	15.3	-28.8	-27.1	4.5	2.7
Group 4: 30 µg/ animal BNT162b1	Mean	9.00	8.558	7.282	2.58	219.42	825.0	43.70
	SD	0.38	0.595	2.998	0.35	18.25	70.3	2.15
	N	5	5	5	5	5	5	5
	%Diff	2.3	4.7	19.7	-19.4	-15.6	-13.1	2.8

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters						
		HGB (mmol/L) [a]	RBC (x10E6/µL) [a]	WBC (x10E3/µL) [a]	Reti (%) [a]	Reti (x10E3/µL) [a]	PLT (x10E3/µL) [a]	HCT (%) [a]
Group 5:	Mean	8.70	8.122	6.830	2.32	187.36	891.4	42.32
100 µg/	SD	0.34	0.443	2.050	0.86	61.82	140.1	1.60
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.1	-0.7	12.3	-27.5	-27.9	-6.1	-0.4
Group 7:	Mean	8.96	8.446	7.120	2.26	190.28	998.4	43.56
100 µg/	SD	0.18	0.428	2.398	0.50	40.16	134.0	0.98
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	1.8	3.3	17.0	-29.4	-26.8	5.1	2.5

[a] - Anova & Dunnett

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	14.63	80.11	2.35	1.68	0.95	0.28
	SD	6.24	7.20	0.76	0.90	0.28	0.10
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	29.64	60.59	3.35	1.38	4.56	0.45
	SD	3.57	3.27	0.87	0.45	1.85	0.07
	N	10	10	10	10	10	10
	%Diff	102.6	-24.4	42.6	-17.9	380.0	60.7
Group 3: 10 µg/ animal BNT162a1	Mean	12.96	80.53	2.71	1.25	2.16	0.37
	SD	3.62	4.40	0.66	0.41	0.60	0.09
	N	10	10	10	10	10	10
	%Diff	-11.4	0.5	15.3	-25.6	127.4	32.1
Group 4: 30 µg/ animal BNT162b1	Mean	13.51	80.74	2.17	1.94	1.28	0.35
	SD	3.00	2.85	0.39	0.90	0.23	0.10
	N	10	10	10	10	10	10
	%Diff	-7.7	0.8	-7.7	15.5	34.7	25.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	18.07	74.98	2.22	1.16	3.18	0.36
100 µg/	SD	7.76	9.53	0.59	0.43	2.32	0.10
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	23.5	-6.4	-5.5	-31.0	234.7	28.6
Group 6:	Mean	22.94	68.08	3.68	1.45	3.39	0.44
30 µg/	SD	3.18	3.41	0.86	0.66	1.06	0.12
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	56.8	-15.0	56.6	-13.7	256.8	57.1
Group 7:	Mean	23.67	68.70	2.20	1.58	3.47	0.39
100 µg/	SD	6.09	7.33	0.73	0.63	1.58	0.09
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	61.8	-14.2	-6.4	-6.0	265.3	39.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	43.23	47.54	2.53	0.59	5.74	0.37
	SD	6.69	6.97	0.69	0.22	1.20	0.11
	N	10	10	10	10	10	10
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	14.55	80.19	2.71	1.28	1.00	0.23
	SD	5.97	6.30	0.59	0.40	0.35	0.08
	N	10	10	10	10	10	10
		-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	44.23	46.59	2.40	0.71	5.65	0.42
	SD	7.15	7.68	0.82	0.18	2.28	0.11
	N	10	10	10	10	10	10
	%Diff	204.0	-41.9	-11.4	-44.5	465.0	82.6
Group 3: 10 µg/ animal BNT162a1	Mean	38.09	51.89	4.03	1.46	4.18	0.37
	SD	5.11	5.85	0.78	1.09	2.42	0.11
	N	10	10	10	10	10	10
	%Diff	161.8	-35.3	48.7	14.1	318.0	60.9
Group 4: 30 µg/ animal BNT162b1	Mean	42.95	47.52	3.49	2.50	3.24	0.32
	SD	9.45	9.74	0.81	0.69	1.07	0.06
	N	10	10	10	10	10	10
	%Diff	195.2	-40.7	28.8	95.3	224.0	39.1

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	48.05	41.13	2.82	3.52	4.20	0.30
100 µg/	SD	6.00	6.95	0.63	0.93	1.82	0.08
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	230.2	-48.7	4.1	175.0	320.0	30.4
Group 7:	Mean	48.70	41.65	2.01	3.80	3.59	0.26
100 µg/	SD	8.05	8.29	0.59	1.03	1.17	0.05
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	234.7	-48.1	-25.8	196.9	259.0	13.0

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 6: 30 µg/ animal BNT162c1	Mean	14.32	79.76	2.78	2.00	0.94	0.24
	SD	3.47	4.06	0.72	0.78	0.29	0.09
	N	5	5	5	5	5	5
		-	-	-	-	-	-

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 1: Control	Mean	15.58	77.06	3.12	3.06	0.98	0.24
	SD	5.05	6.10	0.66	2.05	0.30	0.05
	N	5	5	5	5	5	5
	-						
Group 2: 30 µg/ animal BNT162a1	Mean	15.88	78.66	2.52	1.58	1.12	0.26
	SD	2.77	2.35	0.64	0.44	0.34	0.09
	N	5	5	5	5	5	5
	%Diff	1.9	2.1	-19.2	-48.4	14.3	8.3
Group 3: 10 µg/ animal BNT162a1	Mean	14.96	78.66	3.12	2.06	1.00	0.22
	SD	3.15	4.86	0.70	1.78	0.28	0.11
	N	5	5	5	5	5	5
	%Diff	-4.0	2.1	0.0	-32.7	2.0	-8.3
Group 4: 30 µg/ animal BNT162b1	Mean	18.62	74.60	3.04	2.42	1.10	0.22
	SD	4.94	5.81	0.55	1.53	0.37	0.08
	N	5	5	5	5	5	5
	%Diff	19.5	-3.2	-2.6	-20.9	12.2	-8.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
Group 5:	Mean	18.20	75.92	3.22	1.50	0.96	0.18
100 µg/	SD	5.42	5.59	0.64	0.20	0.17	0.08
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	16.8	-1.5	3.2	-51.0	-2.0	-25.0
Group 7:	Mean	17.80	76.60	2.40	2.04	0.92	0.26
100 µg/	SD	3.87	4.05	0.34	0.69	0.18	0.09
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	14.2	-0.6	-23.1	-33.3	-6.1	8.3

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a1]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	1.112	6.872	0.190	0.134	0.087	0.026
	SD	0.328	3.137	0.067	0.058	0.059	0.018
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	3.837**	7.798	0.436**	0.175	0.587**	0.057**
	SD	0.761	0.963	0.150	0.050	0.239	0.013
	N	10	10	10	10	10	10
	%Diff	245.1	13.5	129.5	30.6	574.7	119.2
Group 3: 10 µg/ animal BNT162a1	Mean	1.109	7.055	0.228	0.104	0.186**	0.036
	SD	0.388	2.172	0.064	0.035	0.072	0.018
	N	10	10	10	10	10	10
	%Diff	-0.3	2.7	20.0	-22.4	113.8	38.5
Group 4: 30 µg/ animal BNT162b1	Mean	1.125	6.709	0.183	0.158	0.108	0.030
	SD	0.346	1.515	0.059	0.065	0.033	0.014
	N	10	10	10	10	10	10
	%Diff	1.2	-2.4	-3.7	17.9	24.1	15.4

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0766195

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.734	6.663	0.204	0.107	0.305**	0.033
100 µg/	SD	1.075	0.964	0.070	0.047	0.270	0.012
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	55.9	-3.0	7.4	-20.1	250.6	26.9
Group 6:	Mean	2.278**	6.865	0.368**	0.137	0.334**	0.047**
30 µg/	SD	0.619	2.142	0.128	0.040	0.130	0.017
animal	N	10	10	10	10	10	10
BNT162c1	%Diff	104.9	-0.1	93.7	2.2	283.9	80.8
Group 7:	Mean	2.523**	7.082	0.223	0.162	0.365**	0.043*
100 µg/	SD	1.276	1.693	0.077	0.074	0.205	0.016
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	126.9	3.1	17.4	20.9	319.5	65.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766196

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	6.552 n	7.308 n	0.386 n	0.092 n	0.870 n	0.055 n
	SD	1.209	1.937	0.118	0.038	0.215	0.021
	N	10	10	10	10	10	10
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766197

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a1]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a2]
Group 1: Control	Mean	0.945	5.784	0.189	0.094	0.077	0.019
	SD	0.228	2.222	0.063	0.048	0.044	0.009
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	6.515**	6.586	0.373*	0.099	0.864**	0.060**
	SD	2.556	1.428	0.239	0.032	0.511	0.028
	N	10	10	10	10	10	10
	%Diff	589.4	13.9	97.4	5.3	1022.1	215.8
Group 3: 10 µg/ animal BNT162a1	Mean	4.139**	5.771	0.438**	0.152*	0.478**	0.039*
	SD	0.842	1.657	0.119	0.088	0.330	0.014
	N	10	10	10	10	10	10
	%Diff	338.0	-0.2	131.7	61.7	520.8	105.3
Group 4: 30 µg/ animal BNT162b1	Mean	5.539**	5.982	0.443**	0.308**	0.429**	0.042**
	SD	2.191	1.845	0.183	0.088	0.214	0.020
	N	10	10	10	10	10	10
	%Diff	486.1	3.4	134.4	227.7	457.1	121.1

[a] - Anova & Dunnett(Log): * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Rank): * = p ≤ 0.05; ** = p ≤ 0.01

FDA-CBER-2021-5683-0766198

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	6.958**	5.865	0.404**	0.508**	0.627**	0.043**
100 µg/	SD	1.735	1.083	0.129	0.152	0.354	0.018
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	636.3	1.4	113.8	440.4	714.3	126.3
Group 7:	Mean	7.369**	6.174	0.305	0.573**	0.535**	0.039*
100 µg/	SD	2.215	1.707	0.135	0.182	0.200	0.014
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	679.8	6.7	61.4	509.6	594.8	105.3

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

FDA-CBER-2021-5683-0766199

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	0.802 n	4.384 n	0.160 n	0.104 n	0.050 n	0.014 n
	SD	0.344	1.134	0.090	0.035	0.016	0.005
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766200

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 1: Control	Mean	0.938	4.712	0.186	0.170	0.060	0.014
	SD	0.301	1.330	0.052	0.103	0.029	0.005
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.176	6.014	0.200	0.120	0.088	0.022
	SD	0.465	2.369	0.113	0.052	0.037	0.013
	N	5	5	5	5	5	5
	%Diff	25.4	27.6	7.5	-29.4	46.7	57.1
Group 3: 10 µg/ animal BNT162a1	Mean	1.008	5.566	0.222	0.126	0.072	0.014
	SD	0.223	1.919	0.100	0.076	0.037	0.011
	N	5	5	5	5	5	5
	%Diff	7.5	18.1	19.4	-25.9	20.0	0.0
Group 4: 30 µg/ animal BNT162b1	Mean	1.268	5.536	0.220	0.158	0.080	0.016
	SD	0.306	2.583	0.086	0.073	0.051	0.015
	N	5	5	5	5	5	5
	%Diff	35.2	17.5	18.3	-7.1	33.3	14.3

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0766201

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		Neut (x10E3/µL) [a]	Lym (x10E3/µL) [a]	Mono (x10E3/µL) [a]	Eos (x10E3/µL) [a]	LUC (x10E3/µL) [a]	Baso (x10E3/µL) [a]
Group 5:	Mean	1.160	5.274	0.212	0.106	0.064	0.012
100 µg/	SD	0.115	2.004	0.047	0.039	0.023	0.008
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	23.7	11.9	14.0	-37.6	6.7	-14.3
Group 7:	Mean	1.224	5.502	0.168	0.140	0.064	0.018
100 µg/	SD	0.357	2.067	0.061	0.050	0.024	0.008
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	30.5	16.8	-9.7	-17.6	6.7	28.6

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0766202

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a1]	MCHC (mmol/L) [a1]
Group 1: Control	Mean	54.73	1.159	21.189
	SD	1.93	0.035	0.234
	N	10	10	10
	-			
Group 2: 30 µg/ animal BNT162a1	Mean	55.43	1.176	21.240
	SD	1.03	0.015	0.223
	N	10	10	10
	%Diff	1.3	1.5	0.2
Group 3: 10 µg/ animal BNT162a1	Mean	54.13	1.170	21.606**
	SD	1.36	0.028	0.281
	N	10	10	10
	%Diff	-1.1	0.9	2.0
Group 4: 30 µg/ animal BNT162b1	Mean	55.21	1.162	21.069
	SD	1.77	0.040	0.264
	N	10	10	10
	%Diff	0.9	0.3	-0.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01

FDA-CBER-2021-5683-0766203

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters		
		MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	53.35	1.138	21.319
	SD	1.61	0.039	0.284
	N	10	10	10
	%Diff	-2.5	-1.8	0.6
Group 6: 30 µg/ animal BNT162c1	Mean	53.25	1.158	21.738**
	SD	1.78	0.040	0.286
	N	10	10	10
	%Diff	-2.7	-0.1	2.6
Group 7: 100 µg/ animal BNT162b2	Mean	53.02	1.157	21.833*
	SD	1.91	0.065	1.040
	N	10	10	10
	%Diff	-3.1	-0.2	3.0

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

FDA-CBER-2021-5683-0766204

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6:	Mean	9.44 n	18.68 n	267.30 n	52.48 n	1.140 n	21.700 n
30 µg/	SD	0.36	0.72	23.49	1.91	0.039	0.193
animal	N	10	10	10	10	10	10
BNT162c1		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766205

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a]	MCV (fL) [a1]	MCH (fmol) [a1]	MCHC (mmol/L) [a1]
Group 1: Control	Mean	9.03	15.08	114.44	55.04	1.149	20.880
	SD	0.40	1.24	58.30	1.43	0.025	0.237
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.13	17.59**	314.00**	55.30	1.149	20.777
	SD	0.47	1.11	24.64	0.94	0.018	0.224
	N	10	10	10	10	10	10
	%Diff	1.1	16.6	174.4	0.5	0.0	-0.5
Group 3: 10 µg/ animal BNT162a1	Mean	8.70	18.59**	279.78*	52.58**	1.121	21.328**
	SD	1.32	1.42	63.93	1.84	0.037	0.362
	N	9	9	9	10	10	10
	%Diff	-3.7	23.3	144.5	-4.5	-2.4	2.1
Group 4: 30 µg/ animal BNT162b1	Mean	9.34	14.74	281.78**	54.53	1.120	20.554*
	SD	0.39	0.70	26.36	2.02	0.043	0.230
	N	9	9	9	10	10	10
	%Diff	3.5	-2.2	146.2	-0.9	-2.5	-1.6

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

FDA-CBER-2021-5683-0766206

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	9.24	17.15**	299.10**	51.86**	1.100**	21.221*
100 µg/	SD	0.53	1.38	32.24	1.49	0.029	0.273
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	2.3	13.7	161.4	-5.8	-4.3	1.6
Group 7:	Mean	9.39	17.81**	297.75**	52.84*	1.116	21.098
100 µg/	SD	0.44	1.01	15.50	1.27	0.023	0.331
animal	N	8	8	8	10	10	10
BNT162b2	%Diff	4.0	18.1	160.2	-4.0	-2.9	1.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766207

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	9.28 n	15.32 n	104.00 n	51.78 n	1.086 n	20.992 n
	SD	0.60	1.09	29.23	1.18	0.036	0.367
	N	5	5	5	5	5	5
		-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766208

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a1]	Fibrinogen (mg/dL) [a2]	MCV (fL) [a1]	MCH (fmol) [a1]	MCHC (mmol/L) [a2]
Group 1: Control	Mean	9.34	17.05	88.25	52.00	1.078	20.718
	SD	0.63	0.64	7.69	1.97	0.030	0.160
	N	5	4	4	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	9.36	15.58	86.78	53.58	1.094	20.402
	SD	0.29	0.80	4.08	1.72	0.025	0.231
	N	5	4	4	5	5	5
	%Diff	0.2	-8.7	-1.7	3.0	1.5	-1.5
Group 3: 10 µg/ animal BNT162a1	Mean	9.26	17.52	116.98	52.50	1.086	20.706
	SD	0.27	1.43	70.19	1.34	0.022	0.205
	N	5	5	4	5	5	5
	%Diff	-0.9	2.8	32.5	1.0	0.7	-0.1
Group 4: 30 µg/ animal BNT162b1	Mean	9.16	16.86	96.84	51.16	1.052	20.634
	SD	0.17	1.53	25.92	1.55	0.044	0.238
	N	5	5	5	5	5	5
	%Diff	-1.9	-1.1	9.7	-1.6	-2.4	-0.4

[a] - Anova & Dunnett(Log)
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0766209

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters					
		PT (Seconds) [a]	aPTT (Seconds) [a]	Fibrinogen (mg/dL) [a]	MCV (fL) [a]	MCH (fmol) [a]	MCHC (mmol/L) [a]
Group 5:	Mean	8.86	17.98	86.80	52.16	1.068	20.516
100 µg/	SD	0.24	1.51	8.98	1.84	0.036	0.249
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-5.1	5.5	-1.6	0.3	-0.9	-1.0
Group 7:	Mean	8.96	16.30	84.68	51.68	1.064	20.608
100 µg/	SD	0.34	0.65	11.39	2.05	0.050	0.235
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-4.1	-4.4	-4.0	-0.6	-1.3	-0.5

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0766210

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a1]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	7.78	0.757	78.02	11.15	20.82
	SD	0.58	0.105	8.25	0.58	1.26
	N	10	10	10	10	10
		-	-	-	-	.
Group 2: 30 µg/ animal BNT162a1	Mean	8.26	0.619*	87.37	11.24	21.90
	SD	0.48	0.097	7.22	0.53	0.92
	N	10	10	10	10	10
	%Diff	6.2	-18.2	12.0	0.8	5.2
Group 3: 10 µg/ animal BNT162a1	Mean	6.92**	0.736	84.49	10.87	23.43**
	SD	0.34	0.150	10.23	0.50	1.16
	N	10	10	10	10	10
	%Diff	-11.1	-2.8	8.3	-2.5	12.5
Group 4: 30 µg/ animal BNT162b1	Mean	7.85	0.770	80.95	11.85	21.46
	SD	0.63	0.099	6.60	0.64	0.88
	N	10	10	10	10	10
	%Diff	0.9	1.7	3.8	6.3	3.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$

FDA-CBER-2021-5683-0766211

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	7.15*	0.748	84.37	11.61	23.80**
100 µg/	SD	0.36	0.088	8.93	0.82	0.78
animal	N	10	10	10	10	10
BNT162b1	%Diff	-8.1	-1.2	8.1	4.1	14.3
Group 6:	Mean	7.19*	0.716	86.49	11.37	23.28**
30 µg/	SD	0.41	0.089	8.46	0.50	0.97
animal	N	10	10	10	10	10
BNT162c1	%Diff	-7.6	-5.4	10.9	2.0	11.8
Group 7:	Mean	7.25	0.733	82.59	11.26	23.91**
100 µg/	SD	0.47	0.095	9.77	0.81	1.04
animal	N	10	10	10	10	10
BNT162b2	%Diff	-6.8	-3.2	5.9	1.0	14.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766212

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	8.64 n	0.484 n	99.52 n	12.17 n	23.57 n
	SD	1.01	0.107	4.66	0.80	0.79
	N	10	10	10	10	10
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766213

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a1]	PDW (%) [a2]	RDW (%) [a1]	MPC (g/dL) [a1]
Group 1: Control	Mean	10.78	1.156	56.63	14.25	17.77
	SD	0.48	0.177	1.84	0.60	1.01
	N	10	10	10	10	10
		-	-	-	-	.
Group 2: 30 µg/ animal BNT162a1	Mean	11.93	0.733**	68.54**	15.83**	19.72**
	SD	1.22	0.153	5.88	0.73	0.85
	N	10	10	10	10	10
	%Diff	10.7	-36.6	21.0	11.1	11.0
Group 3: 10 µg/ animal BNT162a1	Mean	8.93**	0.619**	82.72**	13.01**	20.34**
	SD	0.97	0.135	6.86	0.66	0.86
	N	10	10	10	10	10
	%Diff	-17.2	-46.5	46.1	-8.7	14.5
Group 4: 30 µg/ animal BNT162b1	Mean	10.55	0.924**	61.27	15.12*	19.33**
	SD	0.56	0.134	4.66	0.62	1.00
	N	10	10	10	10	10
	%Diff	-2.1	-20.1	8.2	6.1	8.8

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a2] - Anova & Dunnett(Log): ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	9.34**	0.654**	84.26**	13.30*	21.36**
100 µg/	SD	0.78	0.100	7.72	0.80	0.96
animal	N	10	10	10	10	10
BNT162b1	%Diff	-13.4	-43.4	48.8	-6.7	20.2
Group 7:	Mean	9.53**	0.657**	80.65**	13.37*	21.02**
100 µg/	SD	1.16	0.103	6.96	0.78	0.96
animal	N	10	10	10	10	10
BNT162b2	%Diff	-11.6	-43.2	42.4	-6.2	18.3

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	7.98 n	0.816 n	72.20 n	12.96 n	20.76 n
	SD	0.61	0.084	10.98	0.31	0.91
	N	5	5	5	5	5
		-	-	-	-	.

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 1: Control	Mean	8.50	0.802	66.30	11.64	18.32
	SD	0.49	0.203	5.37	0.55	0.64
	N	5	5	5	5	5
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	8.44	0.788	66.86	13.38**	18.90
	SD	0.53	0.086	5.43	0.54	0.93
	N	5	5	5	5	5
	%Diff	-0.7	-1.7	0.8	14.9	3.2
Group 3: 10 µg/ animal BNT162a1	Mean	8.08	0.798	72.26	13.14**	20.06*
	SD	0.75	0.123	4.94	0.84	0.59
	N	5	5	5	5	5
	%Diff	-4.9	-0.5	9.0	12.9	9.5
Group 4: 30 µg/ animal BNT162b1	Mean	8.66	0.714	73.16	13.08**	19.48
	SD	0.71	0.104	3.43	0.36	0.55
	N	5	5	5	5	5
	%Diff	1.9	-11.0	10.3	12.4	6.3

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Haematological Parameters				
		MPV (fL) [a]	PCT (%) [a]	PDW (%) [a]	RDW (%) [a]	MPC (g/dL) [a]
Group 5:	Mean	7.74	0.692	71.88	13.36**	20.64**
100 µg/	SD	0.38	0.106	11.82	0.23	1.61
animal	N	5	5	5	5	5
BNT162b1	%Diff	-8.9	-13.7	8.4	14.8	12.7
Group 7:	Mean	7.76	0.780	72.34	13.36**	20.96**
100 µg/	SD	0.54	0.146	4.02	0.30	0.86
animal	N	5	5	5	5	5
BNT162b2	%Diff	-8.7	-2.7	9.1	14.8	14.4

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Reticulocyte (Relative)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	2	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Reticulocyte (Relative)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	4	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	HCT	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	5	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	HGB	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	WBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	PLT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	HCT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Reticulocyte (Relative)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	Reticulocyte (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Reticulocyte (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	3	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Reticulocyte (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	4	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	WBC	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	31	6	Male	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	PLT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	HCT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Basophils (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Lymphocytes (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Lymphocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	Monocytes (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	17	2	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Eosinophils (Absolute)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Male	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	5	Male	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Monocytes (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Male	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	MCHC	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	aPTT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Fibrinogen	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	MCV	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Male	aPTT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Fibrinogen	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Fibrinogen	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Male	MCV	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	aPTT	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	31	6	Male	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	MPC	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	MPC	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	5	Male	Platlet Dist Width	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Platlet Dist Width	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	4	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	38	2	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	4	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	7	Male	RDW	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	WBC	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Reticulocyte (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	PLT	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Reticulocyte (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Reticulocyte (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	5	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Reticulocyte (Relative)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Reticulocyte (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	WBC	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	PLT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	HCT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	RBC	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Female	WBC	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Female	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	PLT	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	HGB	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	RBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	WBC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	PLT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	HCT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	HGB	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	RBC	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	WBC	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Reticulocyte (Relative)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Reticulocyte (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	PLT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	HCT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Monocytes (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Female	Basophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Basophils (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	10	6	Female	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	Monocytes (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	2	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	Basophils (Absolute)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Monocytes (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Eosinophils (Absolute)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	3	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Basophils (Absolute)	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	4	Female	Neutrophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Female	Monocytes (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Eosinophils (Absolute)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Large Unclas sified Cells	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Basophils (Absolute)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Monocytes (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Basophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Neutrophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Eosinophils (Absolute)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Large Unclas sified Cells	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Basophils (Absolute)	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	Neutrophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Lymphocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Monocytes (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Eosinophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Large Unclas sified Cells	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Basophils (Absolute)	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	3	Female	MCHC	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	6	Female	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	MCHC	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Female	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Fibrinogen	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Fibrinogen	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	3	Female	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	MCHC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Fibrinogen	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	MCHC	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MCV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MCH	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MCHC	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	aPTT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Fibrinogen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	MCV	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	PT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	aPTT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Fibrinogen	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MCV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MCH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MCHC	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Plateletcrit	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	3	Female	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	MPV	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	MPV	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	MPV	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Platlet Dist Width	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	RDW	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	RDW	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 6-1 Haematological Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	MPV	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Plateletcrit	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Platlet Dist Width	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	RDW	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	MPV	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Plateletcrit	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Platlet Dist Width	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	RDW	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	MPC	n	Anova & Dunnett: n - Inappropriate for statistics
	38	2	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	MPC	*	Anova & Dunnett: * = p ≤ 0.05
	38	4	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01
	38	7	Female	RDW	**	Anova & Dunnett: ** = p ≤ 0.01
	38	7	Female	MPC	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
1	8.4	7.25	7.49	4.2	307.3	973	41.2
2	8.5	6.94	9.22	4.1	286.2	871	40.9
3	8.9	7.45	8.28	5.0	374.2	1090	43.7
4	8.7	7.25	7.25	4.3	311.9	894	42.2
5	8.5	7.61	14.48	4.2	323.2	1017	41.3
11	8.9	7.82	9.07	4.0	316.0	896	43.3
12	8.2	6.51	9.33	5.2	337.1	1124	40.2
13	8.4	7.24	11.08	3.9	283.5	1050	40.9
14	8.9	7.48	8.86	3.1	234.5	1237	43.3
15	8.6	7.15	8.61	4.1	295.7	833	42.2
Mean	8.60	7.270	9.367	4.21	306.96	998.5	41.92
SD	0.24	0.365	2.087	0.58	36.75	129.0	1.21
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
31	8.6	7.29	15.65	1.3	93.2	1254	41.6
32	8.7	7.69	8.76	0.6	47.3	1191	41.7
33	7.8	6.76	7.69	1.3	91.1	976	36.8
34	8.4	7.35	11.30	1.1	81.6	982	40.1
35	8.3	7.17	12.35	0.9	67.4	1105	40.4
41	8.5	6.88	11.97	1.1	74.0	1089	40.5
42	8.6	7.24	12.14	0.8	54.7	941	40.8
43	8.4	7.16	15.07	1.1	81.6	888	41.1
44	8.5	7.39	12.72	1.1	80.0	915	41.5
45	8.5	7.25	9.81	1.1	77.6	876	41.3
Mean	8.43	7.218	11.746	1.04	74.85	1021.7	40.58
SD	0.25	0.260	2.519	0.22	14.71	131.1	1.44
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
61	8.9	7.83	9.50	1.2	95.7	1077	43.1
62	8.5	7.57	8.92	1.6	120.2	1453	41.5
63	8.9	7.76	8.64	1.5	112.8	970	41.7
64	9.3	8.14	14.66	0.7	60.8	905	43.9
65	9.0	7.43	9.12	1.9	139.7	1057	42.4
71	8.4	7.05	11.26	1.7	122.2	1219	39.9
72	9.1	7.88	9.98	1.6	122.3	1116	43.0
73	9.9	8.37	11.06	1.6	132.8	1134	47.4
74	9.1	7.92	12.29	1.5	116.6	1032	43.6
75	8.8	7.59	10.31	1.8	139.7	1223	41.2
Mean	8.99	7.754	10.574	1.51	116.28	1118.6	42.77
SD	0.42	0.371	1.841	0.34	23.50	154.1	2.03
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
91	8.2	7.16	10.05	1.9	137.5	898	40.3
92	8.2	7.12	9.23	2.3	160.9	954	40.7
93	8.3	7.31	10.32	2.8	207.2	1035	39.8
94	8.2	7.29	13.56	1.7	123.7	1200	40.4
95	8.3	7.03	12.80	2.9	206.5	993	40.8
101	8.4	7.16	11.85	2.0	146.3	823	41.0
102	8.1	7.00	7.73	2.5	178.0	1216	40.5
103	7.8	6.81	7.64	2.6	174.1	987	38.7
104	8.3	7.47	9.37	2.6	192.7	888	40.8
105	8.3	6.91	7.46	2.7	184.3	1022	40.9
Mean	8.21	7.126	10.001	2.40	171.12	1001.6	40.39
SD	0.17	0.198	2.166	0.41	28.57	126.9	0.69
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
121	8.9	7.84	12.00	2.1	161.6	902	42.4
122	8.9	7.83	7.14	1.0	76.7	1124	42.3
123	8.5	7.39	13.99	1.7	125.7	1224	41.3
124	8.9	7.54	10.67	1.7	125.7	829	41.9
125	9.2	8.04	9.78	1.5	120.8	1223	44.2
131	9.1	7.69	15.07	1.1	86.1	1182	42.6
132	9.3	8.25	8.29	1.2	100.8	852	45.0
133	8.9	7.82	10.37	1.1	89.0	1060	41.9
134	8.8	7.86	11.47	1.7	136.5	1014	41.7
135	8.8	7.58	10.33	1.4	102.5	1106	42.0
Mean	8.93	7.784	10.911	1.45	112.54	1051.6	42.53
SD	0.23	0.249	2.388	0.35	26.19	148.2	1.17
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
151	9.4	8.06	11.80	1.1	91.8	1060	44.5
152	9.4	7.89	15.19	0.9	71.8	953	44.2
153	8.7	7.68	14.61	0.4	32.0	1008	41.6
154	8.9	7.55	11.33	1.1	85.3	965	41.9
155	8.8	7.59	16.77	1.3	95.2	1212	43.1
161	8.4	7.36	11.35	1.0	74.4	1292	40.4
162	8.6	7.41	9.97	0.9	64.7	1251	41.6
163	8.9	7.97	12.72	1.4	107.6	920	42.3
164	9.2	8.29	13.44	0.8	70.1	1293	43.5
165	9.2	8.16	11.68	1.0	77.7	1039	43.5
Mean	8.95	7.796	12.886	0.99	77.06	1099.3	42.66
SD	0.34	0.323	2.098	0.28	20.59	147.4	1.31
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
181	8.8	7.97	10.79	1.3	101.3	832	41.7
182	8.8	7.42	13.27	1.2	90.5	1033	42.3
183	8.9	7.77	14.25	1.1	89.2	940	42.3
184	9.2	7.73	12.92	1.3	98.0	841	43.4
185	9.4	8.00	10.95	1.4	113.6	994	44.1
191	9.1	7.87	11.76	0.9	71.7	876	42.3
192	9.3	7.97	14.38	0.7	59.3	698	43.0
193	9.2	7.88	12.73	1.1	86.5	955	44.0
194	9.1	7.82	12.30	0.9	70.2	1322	42.0
195	9.3	8.05	14.99	0.9	74.9	998	43.7
Mean	9.11	7.848	12.834	1.08	85.52	948.9	42.88
SD	0.21	0.182	1.431	0.23	16.53	164.8	0.87
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
151	8.9	7.72	13.54	2.4	187.4	643	42.1
152	9.1 I	7.80 I	29.53 I	2.9 I	229.1 I	751 I	43.3 I
153	8.7	7.67	21.69	2.5	189.1	745	41.4
154	8.8	7.78	16.88	3.2	249.3	691	42.5
155	8.5	7.35	23.33	2.7	197.2	887	41.7
156	8.6	7.58	17.76	3.0	229.6	741	40.4
157	8.4	7.62	19.12	2.5	194.3	580	39.6
158	9.3	8.43	17.78	1.9	159.8	537	44.3
159	8.1	7.26	18.15	2.2	162.2	743	37.6
160	9.1	7.87	23.37	1.6	128.7	770	41.7
Mean	8.75	7.708	20.115	2.49	192.67	708.8	41.46
SD	0.37	0.319	4.492	0.50	36.61	100.9	1.90
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
1	9.0	8.01	8.28	3.1	247.1	1176	44.9
2	9.3	7.94	7.33	2.8	222.4	792	46.2
3	9.3	8.00	6.21	3.1	245.1	1391	46.7
4	9.0	7.89	8.21	2.6	202.4	958	43.7
5	8.8	8.12	10.65	2.9	234.1	1264	43.8
6	9.2	7.83	8.48	3.5	271.6	900	45.0
7	9.5	8.28	14.28	3.0	251.7	1065	45.6
8	9.3	7.84	9.22	3.1	241.7	878	46.1
9	8.7	7.45	11.36	3.3	246.5	1217	43.0
10	9.3	8.20	6.88	2.2	183.4	1251	45.3
Mean	9.14	7.956	9.090	2.96	234.60	1089.2	45.03
SD	0.25	0.232	2.418	0.37	25.66	199.5	1.21
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
31	9.3	8.19	22.02	2.5	203.4	959	45.8
32	8.4	7.69	10.09	2.4	184.9	867	41.9
33	8.4	7.48	12.18	2.5	189.9	716	41.3
34	8.2	7.44	20.51	1.6	121.1	778	39.9
35	8.7	7.66	15.07	2.9	219.3	1029	41.8
36	8.6	7.50	14.89	2.9	216.0	855	42.8
37	8.8	7.77	15.55	1.8	142.8	805	42.7
38	8.7	7.72	16.89	2.3	176.0	641	42.7
39	8.7	7.87	16.42	1.8	140.8	525	42.7
40	8.9	7.91	19.18	1.9	154.1	872	42.7
Mean	8.67	7.723	16.280	2.26	174.83	804.7	42.43
SD	0.31	0.229	3.632	0.46	33.86	148.6	1.50
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
61	9.2	8.38	16.81	2.2	180.5	708	43.9
62	8.3	7.55	12.08	2.8	211.1	1226	40.1
63	8.8	8.15	14.49	1.7	136.7	668	41.2
64	8.8	7.98	16.23	2.1	167.8	757	42.1
65	8.5	7.43	10.46	3.0	225.4	872	40.0
66	8.8	8.07	13.49	2.5	203.2	631	41.3
67	8.9	7.91	16.34	2.4	189.0	691	42.1
68	8.9	8.31	15.88	2.8	234.1	818	41.4
69	8.5	7.33	17.27	2.6	192.7	845	39.7
70	8.2	7.33	14.54	2.2	163.4	835	39.2
Mean	8.69	7.844	14.759	2.43	190.39	805.1	41.10
SD	0.31	0.403	2.207	0.39	29.73	169.4	1.40
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
91	8.5	7.72	16.45	2.1	161.0	885	42.3
92	8.6	7.78	11.90	2.1	161.4	876	43.1
93	8.6	7.77	13.19	2.9	221.5	874	42.5
94	8.5	7.78	16.64	2.5	193.6	1320	42.3
95	8.3	7.34	17.38	2.8	202.5	887	40.9
96	8.9	7.87	22.80	2.4	185.6	908	43.3
97	8.8	7.76	12.77	2.8	217.3	1071	42.9
98	8.3	7.25	12.84	2.5	179.0	800	40.7
99	8.9	8.02	9.00	2.2	177.7	703	45.1
100	8.8	8.22	13.15	2.3	186.5	982	43.5
Mean	8.62	7.751	14.612	2.46	188.61	930.6	42.66
SD	0.23	0.285	3.826	0.30	20.68	167.8	1.27
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
121	7.8	7.25	15.87	3.8	278.9	628	37.3
122	8.2	7.67	14.02	3.5	269.2	664	39.3
123	7.7	6.81	19.41	2.8	190.0	1022	36.7
124	7.9	7.12	15.26	2.5	176.2	947	37.8
125	8.2	7.44	17.07	4.1	301.6	877	38.7
126	7.8	7.17	26.77	4.3	311.3	736	36.0
127	8.6	7.87	12.80	2.3	180.2	984	41.0
128	8.5	8.02	14.18	2.4	190.1	716	40.6
129	8.6	8.15	19.16	1.9	155.0	688	41.0
130	8.1	7.61	11.10	2.4	180.4	910	39.5
Mean	8.14	7.511	16.564	3.00	223.29	817.2	38.79
SD	0.34	0.430	4.442	0.85	59.50	145.9	1.80
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
181	8.0	7.56	16.36	2.5	190.8	753	37.9
182	8.1	7.17	14.77	2.7	193.4	801	38.8
183	8.3	7.69	25.89	1.7	132.9	658	40.0
184	8.7	7.78	22.53	1.7	130.1	734	41.3
185	8.9	8.02	22.85	2.0	162.7	739	42.5
186	8.2	7.62	14.24	2.9	220.5	579	38.4
187	8.5	8.09	20.86	2.4	190.3	849	40.1
188	8.5	8.00	16.24	2.1	166.8	1020	40.9
189	8.0	7.40	15.99	2.1	152.9	720	38.4
190	7.9	7.37	29.03	2.6	189.0	861	38.2
Mean	8.31	7.670	19.876	2.27	172.94	771.4	39.65
SD	0.33	0.307	5.114	0.41	28.95	121.1	1.55
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
161	8.7	8.31	8.76	2.6	214.5	1017	41.9
162	8.9	8.35	6.48	2.1	171.5	1117	42.9
163	8.6	8.28	7.67	2.3	193.4	856	41.3
164	8.8	8.73	4.84	2.2	188.6	854	43.6
165	9.0	8.61	6.75	2.8	242.3	1043	43.4
Mean	8.80	8.456	6.900	2.40	202.06	977.4	42.62
SD	0.16	0.201	1.457	0.29	27.22	117.6	0.99
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
11	9.5	9.39	10.47	2.4	225.8	1155	46.3
12	8.6	7.85	9.83	3.4	270.5	940	42.6
13	8.4	8.04	14.52	3.4	270.9	982	42.3
14	9.3	8.88	8.13	2.8	244.4	1115	45.7
15	9.0	8.46	7.68	2.0	169.0	750	44.2
Mean	8.96	8.524	10.126	2.80	236.12	988.4	44.22
SD	0.46	0.626	2.715	0.62	42.05	160.5	1.79
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
41	9.1	8.46	8.92	3.1	264.4	1096	44.4
42	8.7	8.61	7.46	3.4	291.1	1174	43.7
43	8.9	8.50	10.36	2.8	239.5	1161	43.7
44	9.1	8.80	11.26	2.6	226.0	1012	44.6
45	9.2	8.54	8.27	3.3	284.3	1089	45.3
Mean	9.00	8.582	9.254	3.04	261.06	1106.4	44.34
SD	0.20	0.134	1.545	0.34	28.05	64.9	0.67
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
71	8.8	8.19	13.08	3.2	259.3	1227	42.5
72	9.4	9.25	7.55	2.5	235.3	871	45.5
73	9.6	9.11	7.95	2.1	190.5	813	46.9
74	8.9	8.61	10.20	2.5	219.3	1136	44.1
75	8.5	8.24	7.62	2.5	205.9	1153	42.3
Mean	9.04	8.680	9.280	2.56	222.06	1040.0	44.26
SD	0.45	0.487	2.388	0.40	26.58	185.1	1.97
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
101	8.7	8.56	9.70	2.8	243.6	924	42.5
102	8.7	8.53	5.07	2.0	174.0	865	43.2
103	8.1	7.76	8.31	2.9	226.1	1088	39.7
104	8.8	8.88	10.89	2.2	193.1	785	44.4
105	8.5	7.96	6.36	3.4	273.6	1048	42.8
Mean	8.56	8.338	8.066	2.66	222.08	942.0	42.52
SD	0.28	0.463	2.376	0.56	39.64	126.0	1.73
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
131	8.9	8.64	10.03	2.0	169.5	998	44.1
132	9.1	8.84	7.31	2.3	204.3	826	44.6
133	8.5	8.40	10.12	2.2	186.9	994	41.1
134	9.1	8.97	8.60	3.0	270.1	922	45.4
135	8.7	8.49	9.18	2.1	175.2	867	42.6
Mean	8.86	8.668	9.048	2.32	201.20	921.4	43.56
SD	0.26	0.237	1.157	0.40	40.75	76.2	1.71
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
191	9.1	8.99	8.87	2.6	231.3	929	45.2
192	9.3	9.31	12.64	2.5	229.2	1100	45.7
193	8.6	8.37	9.54	2.7	226.4	1081	41.7
194	9.2	8.74	7.19	1.6	142.1	1217	44.6
195	9.2	9.01	13.61	2.6	229.9	808	45.6
Mean	9.08	8.884	10.370	2.40	211.78	1027.0	44.56
SD	0.28	0.351	2.679	0.45	38.99	159.6	1.66
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
1	13.7	80.8	3.0	1.5	0.8	0.3
2	18.9	74.7	3.8	1.5	0.8	0.2
3	14.5	80.5	2.4	1.1	1.2	0.3
4	20.8	72.1	3.2	1.7	2.0	0.2
5	17.6	77.1	3.1	1.0	0.8	0.4
11	16.9	77.1	3.2	1.9	0.7	0.2
12	16.7	77.7	3.1	1.5	0.7	0.2
13	15.5	77.7	4.1	1.4	0.9	0.4
14	12.2	83.6	2.1	0.7	1.1	0.3
15	12.5	82.6	3.0	0.8	0.8	0.3
Mean	15.93	78.39	3.10	1.31	0.98	0.28
SD	2.78	3.54	0.58	0.39	0.39	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
31	25.6	65.2	2.8	0.6	5.4	0.4
32	29.7	64.8	2.5	0.7	2.1	0.3
33	25.5	67.2	2.4	1.3	3.5	0.2
34	29.1	59.1	3.4	1.4	6.7	0.3
35	34.6	55.4	2.5	1.0	6.1	0.4
41	27.7	56.5	4.5	1.4	9.5	0.4
42	35.0	52.4	4.4	0.8	7.1	0.4
43	29.1	60.3	4.2	1.5	4.5	0.4
44	30.9	57.6	3.8	1.0	6.4	0.3
45	23.3	68.9	3.7	0.7	3.3	0.2
Mean	29.05	60.74	3.42	1.04	5.46	0.33
SD	3.79	5.51	0.82	0.34	2.17	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
61	12.8	80.9	3.0	1.0	1.7	0.5
62	14.8	78.1	2.5	1.3	2.9	0.4
63	19.1	74.0	2.8	1.7	1.9	0.5
64	15.1	77.5	3.3	1.2	2.3	0.6
65	19.1	72.2	4.0	1.6	2.7	0.4
71	9.7	85.4	2.2	0.5	1.7	0.5
72	12.3	79.9	3.4	0.7	3.4	0.3
73	9.8	85.1	2.1	0.9	1.7	0.5
74	10.4	84.8	2.3	0.9	1.2	0.4
75	12.7	81.3	2.4	1.6	1.6	0.3
Mean	13.58	79.92	2.80	1.14	2.11	0.44
SD	3.45	4.56	0.62	0.41	0.69	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
91	12.6	80.5	3.0	1.5	2.1	0.3
92	10.6	85.3	2.1	0.7	1.0	0.3
93	12.0	82.0	3.0	0.9	1.6	0.4
94	16.0	78.6	2.0	0.5	2.4	0.4
95	12.2	83.0	2.0	1.1	1.4	0.4
101	17.7	76.7	3.3	1.2	0.8	0.4
102	20.5	73.4	2.2	2.5	1.1	0.3
103	13.4	79.8	2.9	2.0	1.7	0.2
104	13.6	80.9	2.5	1.5	1.2	0.3
105	19.2	75.5	2.7	1.3	1.0	0.3
Mean	14.78	79.57	2.57	1.32	1.43	0.33
SD	3.37	3.61	0.48	0.60	0.52	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
121	12.8	81.6	1.7	1.2	2.3	0.5
122	13.2	81.5	2.1	1.5	1.5	0.3
123	11.4	83.2	1.7	0.7	2.5	0.5
124	15.6	76.7	3.0	1.4	2.8	0.5
125	9.2	87.2	1.0	1.0	1.4	0.2
131	12.4	81.9	2.3	1.7	1.2	0.4
132	12.0	80.2	2.2	0.5	4.6	0.4
133	10.5	85.1	1.7	0.8	1.7	0.2
134	10.6	85.1	1.6	1.1	1.2	0.5
135	13.1	81.5	2.0	1.1	1.9	0.4
Mean	12.08	82.40	1.93	1.10	2.11	0.39
SD	1.79	2.95	0.53	0.37	1.03	0.12
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
151	16.2	76.7	3.7	0.9	2.1	0.4
152	21.7	69.0	5.2	0.6	3.0	0.6
153	20.2	73.8	1.7	0.6	3.3	0.5
154	21.5	65.9	3.7	0.5	8.0	0.3
155	17.5	75.5	2.3	0.8	3.3	0.6
161	19.7	72.3	4.2	1.2	2.2	0.4
162	22.8	70.7	3.0	0.9	2.2	0.4
163	22.0	71.4	2.4	0.9	2.8	0.4
164	19.3	74.9	2.2	0.4	2.6	0.5
165	15.5	77.8	3.4	0.7	2.2	0.4
Mean	19.64	72.80	3.18	0.75	3.17	0.45
SD	2.52	3.68	1.07	0.24	1.76	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
181	20.6	73.4	1.7	0.9	2.9	0.5
182	6.5	89.7	1.2	0.3	1.8	0.5
183	14.0	80.0	1.6	0.6	3.3	0.5
184	15.2	78.0	2.0	1.2	3.1	0.5
185	10.6	83.8	2.0	0.6	2.5	0.5
191	28.0	62.9	2.9	1.5	4.4	0.3
192	19.2	73.4	2.5	1.7	2.7	0.5
193	20.2	73.0	3.2	0.6	2.4	0.6
194	15.0	78.8	2.4	0.7	2.6	0.5
195	8.6	86.5	2.0	0.5	1.9	0.5
Mean	15.79	77.95	2.15	0.86	2.76	0.49
SD	6.43	7.77	0.61	0.46	0.75	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
151	49.4	41.1	2.2	0.4	6.6	0.3
152	38.6 I	53.4 I	3.6 I	0.5 I	2.9 I	1.0 I
153	50.2	40.5	1.5	0.6	6.8	0.4
154	39.6	43.3	5.2	0.4	11.2	0.4
155	38.4	50.2	2.2	0.3	8.5	0.4
156	43.5	45.6	3.6	0.5	6.4	0.2
157	55.8	28.8	3.8	0.8	10.5	0.4
158	53.4	36.4	3.2	0.3	6.3	0.4
159	39.6	46.7	3.8	0.7	8.6	0.6
160	35.2	57.3	2.7	0.3	4.0	0.6
Mean	44.37	44.33	3.18	0.48	7.18	0.47
SD	7.23	8.32	1.06	0.18	2.61	0.22
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
1	12.5	81.3	3.5	1.3	1.1	0.2
2	23.4	70.7	3.4	1.6	0.6	0.3
3	14.4	78.1	4.5	1.8	1.0	0.2
4	19.5	74.1	3.2	1.6	1.2	0.3
5	29.4	64.7	4.0	0.8	0.8	0.3
6	9.8	85.6	2.1	1.3	1.0	0.3
7	13.5	80.1	3.6	0.8	1.5	0.5
8	16.7	78.0	3.2	1.0	0.8	0.4
9	8.7	85.7	3.1	1.1	0.9	0.4
10	13.2	81.3	3.2	1.4	0.6	0.3
Mean	16.11	77.96	3.38	1.27	0.95	0.32
SD	6.39	6.57	0.63	0.34	0.28	0.09
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
31	44.9	41.2	2.9	0.5	10.1	0.5
32	46.7	47.8	3.0	0.5	1.8	0.3
33	47.1	44.7	4.0	0.7	3.2	0.3
34	53.3	34.0	4.8	0.9	6.5	0.5
35	45.3	41.6	3.8	0.6	8.2	0.3
36	53.4	35.8	3.2	0.7	6.7	0.2
37	50.4	42.7	3.1	0.8	2.7	0.4
38	48.2	37.1	3.2	0.6	10.6	0.3
39	48.6	39.1	3.0	0.4	8.5	0.3
40	38.4	48.0	3.7	0.4	9.0	0.6
Mean	47.63	41.20	3.47	0.61	6.73	0.37
SD	4.39	4.79	0.60	0.17	3.16	0.13
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
61	34.5	54.9	5.2	0.4	4.4	0.6
62	46.3	46.3	1.8	0.9	4.3	0.4
63	37.2	54.0	4.4	0.7	3.1	0.5
64	38.4	53.0	5.2	0.8	2.3	0.5
65	33.8	57.2	5.2	1.5	1.8	0.4
66	43.6	49.9	2.0	0.6	3.3	0.6
67	34.7	57.0	4.1	0.8	3.1	0.4
68	36.5	54.8	4.0	0.4	3.9	0.4
69	30.4	58.2	5.6	0.8	4.6	0.4
70	30.2	62.9	4.3	0.6	1.7	0.4
Mean	36.56	54.82	4.18	0.75	3.25	0.46
SD	5.18	4.57	1.32	0.31	1.06	0.08
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
91	43.6	46.9	6.0	1.3	1.8	0.4
92	35.6	56.3	5.1	1.6	1.1	0.4
93	40.1	50.7	5.5	1.6	1.7	0.4
94	48.8	45.4	2.5	1.5	1.5	0.3
95	41.6	50.3	4.5	1.8	1.4	0.4
96	34.2	58.1	4.0	1.2	1.9	0.7
97	30.9	62.1	3.1	1.4	2.2	0.3
98	48.7	45.8	2.1	1.5	1.5	0.3
99	48.6	41.3	5.9	2.2	1.7	0.4
100	34.3	56.9	4.8	2.3	1.3	0.5
Mean	40.64	51.38	4.35	1.64	1.61	0.41
SD	6.72	6.71	1.39	0.36	0.32	0.12
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
121	48.2	42.7	3.1	2.6	3.1	0.3
122	53.8	35.6	3.7	3.4	3.1	0.4
123	47.2	43.5	3.8	1.7	3.3	0.5
124	43.0	47.3	5.0	2.4	1.9	0.4
125	49.3	41.6	3.8	2.7	2.3	0.3
126	58.8	28.9	2.9	2.1	6.8	0.4
127	39.1	52.2	3.6	1.7	3.1	0.4
128	47.9	43.4	3.7	1.3	3.4	0.3
129	46.8	45.8	1.9	1.6	3.5	0.4
130	35.3	57.2	1.9	2.6	2.7	0.3
Mean	46.94	43.82	3.34	2.21	3.32	0.37
SD	6.74	7.90	0.94	0.64	1.32	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
181	58.6	32.4	3.3	2.2	3.3	0.2
182	46.6	48.2	0.9	2.4	1.7	0.2
183	49.6	39.9	3.4	3.1	3.5	0.4
184	54.0	35.3	1.6	3.1	5.6	0.4
185	50.3	41.4	1.2	3.0	3.5	0.6
186	53.0	40.2	2.7	1.8	2.0	0.2
187	54.4	35.6	3.6	3.7	2.5	0.3
188	53.2	38.9	2.9	2.6	2.1	0.4
189	49.5	40.7	3.3	4.1	2.1	0.3
190	49.9	39.2	2.4	2.3	5.8	0.4
Mean	51.91	39.18	2.53	2.83	3.21	0.34
SD	3.40	4.27	0.98	0.71	1.46	0.13
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
161	23.7	69.9	3.6	1.5	1.0	0.3
162	22.7	72.4	2.6	1.5	0.5	0.2
163	21.0	73.1	3.3	1.7	0.9	0.1
164	20.0	73.4	3.7	1.7	0.9	0.3
165	18.1	77.1	2.5	1.3	0.8	0.2
Mean	21.10	73.18	3.14	1.54	0.82	0.22
SD	2.21	2.59	0.56	0.17	0.19	0.08
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
11	18.0	75.1	3.6	2.0	1.1	0.3
12	13.0	80.9	3.0	1.9	0.9	0.3
13	20.9	70.7	4.6	2.6	1.0	0.3
14	18.5	76.2	2.7	0.9	1.5	0.2
15	17.3	77.2	2.7	1.5	0.9	0.3
Mean	17.54	76.02	3.32	1.78	1.08	0.28
SD	2.88	3.69	0.80	0.63	0.25	0.04
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
41	14.1	78.7	3.5	2.2	1.2	0.2
42	18.9	76.0	2.9	1.2	0.9	0.2
43	14.2	77.2	5.0	1.3	2.0	0.3
44	16.0	76.9	3.6	1.7	1.4	0.4
45	13.1	80.1	3.7	1.0	1.8	0.4
Mean	15.26	77.78	3.74	1.48	1.46	0.30
SD	2.29	1.62	0.77	0.48	0.44	0.10
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
71	10.8	84.7	2.1	0.9	1.2	0.3
72	19.7	73.7	4.4	1.2	0.8	0.2
73	17.5	76.4	3.1	2.1	0.7	0.2
74	16.2	78.3	2.9	1.4	0.9	0.2
75	14.5	79.8	2.4	2.1	1.0	0.1
Mean	15.74	78.58	2.98	1.54	0.92	0.20
SD	3.35	4.11	0.89	0.54	0.19	0.07
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
101	21.6	70.8	4.7	1.7	0.9	0.3
102	28.3	65.7	3.3	1.9	0.6	0.2
103	13.9	78.2	4.1	2.6	1.0	0.3
104	15.1	79.0	2.5	2.0	1.1	0.3
105	20.8	72.7	3.1	1.9	1.4	0.2
Mean	19.94	73.28	3.54	2.02	1.00	0.26
SD	5.77	5.50	0.86	0.34	0.29	0.05
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
131	25.6	68.3	2.3	2.8	0.7	0.4
132	20.1	74.6	3.2	0.9	0.9	0.2
133	14.6	79.8	2.3	1.7	1.2	0.3
134	18.8	76.3	2.3	1.6	0.8	0.2
135	20.2	75.1	2.5	1.4	0.7	0.1
Mean	19.86	74.82	2.52	1.68	0.86	0.24
SD	3.93	4.17	0.39	0.70	0.21	0.11
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
191	28.5	64.7	3.9	2.1	0.6	0.3
192	15.5	78.2	2.1	2.4	1.5	0.3
193	20.2	72.9	4.0	1.8	0.8	0.3
194	11.3	82.3	3.0	1.6	1.6	0.2
195	14.2	81.1	2.5	0.9	1.0	0.3
Mean	17.94	75.84	3.10	1.76	1.10	0.28
SD	6.72	7.21	0.84	0.57	0.44	0.04
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
1	1.03	6.05	0.22	0.11	0.06	0.02
2	1.74	6.89	0.35	0.14	0.08	0.02
3	1.20	6.67	0.20	0.09	0.10	0.02
4	1.51	5.23	0.23	0.13	0.14	0.01
5	2.55	11.17	0.45	0.15	0.11	0.05
11	1.53	6.99	0.29	0.17	0.06	0.02
12	1.56	7.25	0.29	0.14	0.07	0.02
13	1.72	8.62	0.45	0.15	0.10	0.04
14	1.08	7.40	0.18	0.06	0.10	0.03
15	1.07	7.11	0.26	0.07	0.07	0.03
Mean	1.499	7.338	0.292	0.121	0.089	0.026
SD	0.458	1.608	0.097	0.037	0.026	0.012
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
31	4.01	10.21	0.43	0.10	0.84	0.06
32	2.60	5.68	0.22	0.06	0.18	0.02
33	1.96	5.17	0.18	0.10	0.27	0.01
34	3.29	6.68	0.38	0.16	0.76	0.03
35	4.27	6.84	0.31	0.12	0.76	0.05
41	3.32	6.76	0.53	0.17	1.14	0.04
42	4.25	6.36	0.54	0.09	0.86	0.05
43	4.39	9.09	0.63	0.22	0.67	0.06
44	3.93	7.32	0.48	0.13	0.82	0.04
45	2.28	6.76	0.36	0.06	0.33	0.02
Mean	3.430	7.087	0.406	0.121	0.663	0.038
SD	0.888	1.507	0.144	0.051	0.305	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
61	1.22	7.68	0.29	0.10	0.16	0.05
62	1.32	6.96	0.23	0.12	0.26	0.03
63	1.65	6.39	0.24	0.15	0.16	0.04
64	2.22	11.37	0.48	0.17	0.34	0.09
65	1.74	6.58	0.37	0.15	0.24	0.04
71	1.09	9.62	0.25	0.05	0.20	0.05
72	1.23	7.97	0.34	0.07	0.34	0.03
73	1.08	9.41	0.23	0.10	0.18	0.06
74	1.28	10.42	0.28	0.11	0.15	0.05
75	1.31	8.39	0.25	0.17	0.16	0.03
Mean	1.414	8.479	0.296	0.119	0.219	0.047
SD	0.355	1.682	0.080	0.041	0.073	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
91	1.26	8.09	0.30	0.15	0.21	0.03
92	0.98	7.87	0.19	0.06	0.09	0.03
93	1.24	8.46	0.31	0.09	0.16	0.05
94	2.17	10.65	0.28	0.07	0.33	0.06
95	1.57	10.62	0.25	0.14	0.18	0.05
101	2.10	9.09	0.39	0.14	0.09	0.04
102	1.59	5.67	0.17	0.19	0.09	0.02
103	1.02	6.10	0.22	0.16	0.13	0.02
104	1.28	7.58	0.24	0.14	0.11	0.03
105	1.43	5.63	0.20	0.10	0.07	0.02
Mean	1.464	7.976	0.255	0.124	0.146	0.035
SD	0.407	1.830	0.067	0.042	0.079	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
121	1.53	9.79	0.20	0.14	0.28	0.06
122	0.94	5.82	0.15	0.11	0.10	0.02
123	1.60	11.64	0.24	0.09	0.35	0.07
124	1.66	8.18	0.32	0.15	0.30	0.05
125	0.90	8.53	0.10	0.10	0.13	0.02
131	1.88	12.34	0.35	0.25	0.19	0.06
132	1.00	6.65	0.18	0.04	0.38	0.03
133	1.09	8.83	0.17	0.08	0.17	0.02
134	1.21	9.76	0.18	0.12	0.14	0.05
135	1.36	8.42	0.20	0.11	0.20	0.04
Mean	1.317	8.996	0.209	0.119	0.224	0.042
SD	0.340	2.006	0.076	0.055	0.097	0.019
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
151	1.91	9.06	0.44	0.11	0.25	0.05
152	3.29	10.48	0.78	0.10	0.46	0.08
153	2.95	10.77	0.24	0.09	0.48	0.07
154	2.44	7.47	0.42	0.06	0.91	0.04
155	2.93	12.66	0.38	0.14	0.56	0.10
161	2.24	8.20	0.48	0.13	0.25	0.05
162	2.27	7.05	0.30	0.09	0.22	0.04
163	2.80	9.08	0.31	0.12	0.36	0.06
164	2.60	10.07	0.30	0.05	0.35	0.07
165	1.81	9.09	0.40	0.08	0.26	0.04
Mean	2.524	9.393	0.405	0.097	0.410	0.060
SD	0.478	1.671	0.152	0.029	0.210	0.020
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
181	2.23	7.92	0.18	0.10	0.32	0.05
182	0.86	11.91	0.16	0.04	0.24	0.06
183	1.99	11.40	0.22	0.08	0.47	0.08
184	1.97	10.08	0.25	0.15	0.41	0.06
185	1.17	9.17	0.21	0.07	0.27	0.06
191	3.29	7.40	0.34	0.17	0.52	0.04
192	2.76	10.56	0.36	0.24	0.39	0.08
193	2.57	9.29	0.41	0.08	0.30	0.08
194	1.85	9.70	0.30	0.09	0.32	0.06
195	1.29	12.96	0.30	0.08	0.28	0.08
Mean	1.998	10.039	0.273	0.110	0.352	0.065
SD	0.755	1.733	0.082	0.059	0.092	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
151	6.69	5.57	0.30	0.05	0.89	0.04
152	11.39 I	15.78 I	1.07 I	0.13 I	0.86 I	0.31 I
153	10.89	8.79	0.33	0.12	1.47	0.08
154	6.68	7.30	0.87	0.06	1.89	0.07
155	8.97	11.71	0.51	0.07	1.97	0.10
156	7.73	8.11	0.64	0.10	1.14	0.04
157	10.67	5.50	0.74	0.15	2.00	0.07
158	9.50	6.47	0.56	0.05	1.13	0.07
159	7.19	8.48	0.68	0.13	1.56	0.11
160	8.22	13.39	0.62	0.08	0.93	0.13
Mean	8.793	9.110	0.632	0.094	1.384	0.102
SD	1.767	3.446	0.232	0.037	0.455	0.078
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
1	1.04	6.73	0.29	0.11	0.09	0.02
2	1.72	5.18	0.25	0.11	0.04	0.02
3	0.90	4.85	0.28	0.11	0.06	0.02
4	1.60	6.08	0.26	0.14	0.10	0.02
5	3.13	6.89	0.43	0.09	0.08	0.03
6	0.83	7.25	0.18	0.11	0.08	0.03
7	1.92	11.44	0.52	0.11	0.22	0.06
8	1.54	7.19	0.29	0.09	0.07	0.03
9	0.99	9.74	0.36	0.12	0.10	0.05
10	0.91	5.59	0.22	0.10	0.04	0.02
Mean	1.458	7.094	0.308	0.109	0.088	0.030
SD	0.707	2.057	0.102	0.014	0.051	0.014
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
31	9.88	9.07	0.64	0.11	2.21	0.10
32	4.71	4.82	0.30	0.05	0.18	0.03
33	5.73	5.44	0.49	0.09	0.38	0.04
34	10.94	6.98	0.99	0.18	1.33	0.09
35	6.83	6.27	0.58	0.10	1.24	0.05
36	7.95	5.34	0.48	0.11	0.99	0.03
37	7.84	6.64	0.48	0.12	0.42	0.07
38	8.13	6.27	0.53	0.11	1.79	0.05
39	7.98	6.42	0.49	0.07	1.40	0.06
40	7.37	9.20	0.71	0.07	1.73	0.11
Mean	7.736	6.645	0.569	0.101	1.167	0.063
SD	1.803	1.466	0.184	0.036	0.672	0.029
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
61	5.81	9.22	0.87	0.07	0.74	0.10
62	5.60	5.59	0.22	0.10	0.52	0.05
63	5.39	7.83	0.64	0.10	0.45	0.08
64	6.22	8.60	0.84	0.13	0.37	0.07
65	3.54	5.99	0.54	0.16	0.19	0.04
66	5.88	6.73	0.27	0.09	0.45	0.08
67	5.66	9.31	0.67	0.13	0.50	0.07
68	5.79	8.69	0.63	0.07	0.63	0.07
69	5.26	10.05	0.97	0.13	0.80	0.07
70	4.38	9.15	0.62	0.08	0.24	0.06
Mean	5.353	8.116	0.627	0.106	0.489	0.069
SD	0.805	1.525	0.241	0.030	0.197	0.017
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
91	7.18	7.71	0.98	0.21	0.30	0.07
92	4.23	6.70	0.60	0.19	0.13	0.05
93	5.28	6.69	0.72	0.20	0.23	0.05
94	8.12	7.55	0.42	0.25	0.24	0.05
95	7.23	8.74	0.77	0.32	0.25	0.06
96	7.80	13.24	0.91	0.26	0.43	0.15
97	3.95	7.93	0.40	0.18	0.28	0.04
98	6.26	5.88	0.27	0.20	0.19	0.04
99	4.37	3.72	0.53	0.20	0.15	0.03
100	4.51	7.48	0.63	0.30	0.17	0.06
Mean	5.893	7.564	0.623	0.231	0.237	0.060
SD	1.610	2.424	0.227	0.049	0.088	0.034
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
121	7.65	6.77	0.49	0.41	0.49	0.05
122	7.55	4.99	0.52	0.47	0.44	0.05
123	9.16	8.44	0.74	0.32	0.65	0.09
124	6.57	7.21	0.77	0.37	0.29	0.06
125	8.42	7.09	0.64	0.47	0.39	0.06
126	15.75	7.75	0.77	0.56	1.83	0.12
127	5.01	6.68	0.46	0.22	0.39	0.05
128	6.79	6.16	0.52	0.18	0.49	0.04
129	8.98	8.77	0.36	0.31	0.67	0.07
130	3.92	6.35	0.21	0.29	0.30	0.04
Mean	7.980	7.021	0.548	0.360	0.594	0.063
SD	3.197	1.113	0.184	0.119	0.453	0.025
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
181	9.59	5.30	0.54	0.35	0.54	0.04
182	6.88	7.11	0.13	0.35	0.26	0.03
183	12.85	10.34	0.89	0.81	0.91	0.10
184	12.17	7.96	0.36	0.70	1.25	0.09
185	11.50	9.46	0.27	0.68	0.79	0.15
186	7.55	5.73	0.39	0.26	0.29	0.03
187	11.35	7.42	0.74	0.76	0.52	0.07
188	8.63	6.31	0.47	0.42	0.34	0.06
189	7.91	6.51	0.53	0.65	0.34	0.05
190	14.48	11.38	0.70	0.68	1.67	0.12
Mean	10.291	7.752	0.502	0.566	0.691	0.074
SD	2.545	2.029	0.230	0.199	0.468	0.040
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
161	2.08	6.13	0.31	0.13	0.08	0.03
162	1.47	4.69	0.17	0.10	0.04	0.01
163	1.61	5.60	0.25	0.13	0.07	0.01
164	0.97	3.55	0.18	0.08	0.05	0.02
165	1.22	5.20	0.17	0.09	0.06	0.01
Mean	1.470	5.034	0.216	0.106	0.060	0.016
SD	0.420	0.984	0.062	0.023	0.016	0.009
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
11	1.88	7.86	0.38	0.21	0.11	0.03
12	1.28	7.95	0.29	0.18	0.09	0.03
13	3.03	10.26	0.66	0.38	0.14	0.05
14	1.51	6.19	0.22	0.08	0.12	0.01
15	1.33	5.93	0.21	0.12	0.07	0.02
Mean	1.806	7.638	0.352	0.194	0.106	0.028
SD	0.724	1.735	0.185	0.116	0.027	0.015
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766294

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
41	1.26	7.02	0.31	0.20	0.11	0.02
42	1.41	5.66	0.21	0.09	0.06	0.02
43	1.47	8.00	0.52	0.13	0.21	0.03
44	1.80	8.66	0.41	0.19	0.16	0.04
45	1.08	6.63	0.30	0.08	0.15	0.03
Mean	1.404	7.194	0.350	0.138	0.138	0.028
SD	0.268	1.173	0.119	0.055	0.056	0.008
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766295

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
71	1.41	11.07	0.28	0.12	0.16	0.04
72	1.49	5.57	0.33	0.09	0.06	0.01
73	1.39	6.08	0.25	0.16	0.06	0.01
74	1.65	7.99	0.30	0.14	0.09	0.02
75	1.11	6.08	0.18	0.16	0.08	0.01
Mean	1.410	7.358	0.268	0.134	0.090	0.018
SD	0.196	2.272	0.057	0.030	0.041	0.013
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766296

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
101	2.09	6.87	0.45	0.16	0.09	0.03
102	1.44	3.33	0.17	0.09	0.03	0.01
103	1.15	6.50	0.34	0.21	0.08	0.02
104	1.65	8.60	0.27	0.22	0.12	0.03
105	1.32	4.62	0.20	0.12	0.09	0.01
Mean	1.530	5.984	0.286	0.160	0.082	0.020
SD	0.362	2.049	0.113	0.056	0.033	0.010
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766297

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
131	2.57	6.85	0.23	0.28	0.07	0.04
132	1.47	5.46	0.23	0.07	0.06	0.02
133	1.48	8.08	0.23	0.17	0.12	0.03
134	1.62	6.56	0.20	0.14	0.07	0.01
135	1.85	6.89	0.23	0.13	0.06	0.01
Mean	1.798	6.768	0.224	0.158	0.076	0.022
SD	0.458	0.935	0.013	0.077	0.025	0.013
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766298

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
191	2.52	5.74	0.35	0.18	0.05	0.02
192	1.96	9.88	0.27	0.31	0.19	0.04
193	1.93	6.95	0.38	0.18	0.08	0.03
194	0.81	5.92	0.21	0.11	0.12	0.01
195	1.93	11.04	0.34	0.12	0.13	0.05
Mean	1.830	7.906	0.310	0.180	0.114	0.030
SD	0.623	2.412	0.069	0.080	0.053	0.016
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766299

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
1	56.8	1.16	20.34
2	58.9	1.22	20.67
3	58.7	1.19	20.28
4	58.2	1.19	20.49
5	54.3	1.11	20.52
11	55.4	1.14	20.62
12	61.8	1.26	20.32
13	56.5	1.17	20.62
14	57.8	1.20	20.66
15	59.0	1.20	20.38
Mean	57.74	1.184	20.490
SD	2.12	0.042	0.150
N	10	10	10

FDA-CBER-2021-5683-0766300

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
31	57.1	1.17	20.57
32	54.2	1.12	20.75
33	54.4	1.15	21.20
34	54.5	1.15	21.05
35	56.4	1.16	20.66
41	58.8	1.23	20.95
42	56.4	1.18	20.98
43	57.4	1.18	20.49
44	56.2	1.16	20.58
45	57.0	1.17	20.59
Mean	56.24	1.167	20.782
SD	1.48	0.028	0.244
N	10	10	10

FDA-CBER-2021-5683-0766301

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
61	55.0	1.14	20.64
62	54.9	1.12	20.49
63	53.7	1.14	21.28
64	54.0	1.15	21.25
65	57.1	1.21	21.21
71	56.6	1.20	21.13
72	54.6	1.16	21.21
73	56.5	1.18	20.92
74	55.1	1.15	20.90
75	54.4	1.16	21.31
Mean	55.19	1.161	21.034
SD	1.16	0.028	0.286
N	10	10	10

FDA-CBER-2021-5683-0766302

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
91	56.3	1.15	20.35
92	57.2	1.15	20.15
93	54.4	1.14	20.92
94	55.5	1.13	20.36
95	58.0	1.18	20.38
101	57.3	1.17	20.50
102	57.8	1.16	20.10
103	56.9	1.15	20.20
104	54.6	1.11	20.35
105	59.3	1.20	20.31
Mean	56.73	1.154	20.362
SD	1.55	0.025	0.229
N	10	10	10

FDA-CBER-2021-5683-0766303

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
121	54.1	1.13	20.95
122	54.1	1.14	21.06
123	55.8	1.16	20.71
124	55.5	1.19	21.36
125	55.0	1.15	20.90
131	55.3	1.18	21.42
132	54.6	1.12	20.60
133	53.5	1.13	21.15
134	53.0	1.12	21.20
135	55.4	1.17	21.04
Mean	54.63	1.149	21.039
SD	0.93	0.025	0.261
N	10	10	10

FDA-CBER-2021-5683-0766304

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
151	55.2	1.17	21.14
152	56.0	1.19	21.22
153	54.2	1.14	20.94
154	55.5	1.18	21.16
155	56.7	1.16	20.51
161	55.0	1.14	20.73
162	56.1	1.16	20.70
163	53.0	1.12	21.11
164	52.5	1.11	21.21
165	53.3	1.13	21.18
Mean	54.75	1.150	20.990
SD	1.44	0.026	0.256
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
181	52.4	1.11	21.18
182	57.1	1.19	20.83
183	54.4	1.15	21.07
184	56.2	1.19	21.14
185	55.1	1.17	21.28
191	53.8	1.15	21.46
192	54.0	1.17	21.65
193	55.8	1.17	20.96
194	53.7	1.16	21.58
195	54.3	1.16	21.37
Mean	54.68	1.162	21.252
SD	1.38	0.023	0.266
N	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
151	10.2	18.6	290.0	54.6	1.15	21.07
152	9.7	17.1	304.0	55.5 I	1.16 I	20.95 I
153	10.1	18.5	326.0	54.0	1.13	20.94
154	10.2	17.2	299.0	54.6	1.14	20.78
155	9.4	18.0	292.0	56.7	1.15	20.37
156	9.5	19.3	327.0	53.4	1.13	21.15
157	10.3	17.4	310.0	51.9	1.10	21.23
158	10.5	18.8	281.0	52.6	1.11	21.05
159	9.7	18.7	275.0	51.7	1.11	21.45
160	9.5	18.9	278.0	53.0	1.15	21.71
Mean	9.91	18.25	298.20	53.80	1.133	21.070
SD	0.39	0.78	18.63	1.59	0.021	0.364
N	10	10	10	10	10	10

I = Include

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
1	9.8	14.6	97.9	56.0	1.13	20.16
2	NV !	NV !	NV !	58.1	1.17	20.05
3	9.2	18.6	117.0	58.4	1.17	19.96
4	9.7	15.4	119.0	55.4	1.14	20.62
5	9.3	18.2	107.0	54.0	1.09	20.20
6	9.7	14.3	109.0	57.5	1.17	20.35
7	9.6	14.3	109.0	55.0	1.15	20.83
8	9.4	14.1	99.9	58.7	1.19	20.21
9	9.6	14.2	88.3	57.8	1.17	20.27
10	9.8	14.2	108.0	55.2	1.13	20.54
Mean	9.57	15.32	106.12	56.61	1.151	20.319
SD	0.22	1.79	9.55	1.67	0.029	0.270
N	9	9	9	10	10	10

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
31	8.4	18.0	301.0	55.9	1.14	20.33
32	9.5	16.7	292.0	54.4	1.09	20.02
33	8.8	14.6	339.0	55.3	1.12	20.29
34	10.5	18.5	316.0	53.7	1.11	20.59
35	9.5	18.1	301.0	54.6	1.13	20.69
36	9.5	17.5	335.0	57.2	1.15	20.10
37	9.9	17.9	322.0	54.9	1.13	20.55
38	10.1	19.5	263.0	55.3	1.12	20.28
39	9.4	19.2	326.0	54.3	1.11	20.37
40	9.3	17.0	296.0	54.0	1.12	20.81
Mean	9.49	17.70	309.10	54.96	1.122	20.403
SD	0.60	1.40	23.06	1.03	0.017	0.253
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
61	10.1	19.5	248.0	52.4	1.10	21.07
62	NV !	NV !	NV !	53.2	1.10	20.65
63	9.9	20.9	253.0	50.6	1.08	21.30
64	9.2	17.3	296.0	52.8	1.11	20.94
65	10.1	16.9	271.0	53.9	1.14	21.18
66	9.2	18.3	287.0	51.2	1.09	21.29
67	9.6	17.0	254.0	53.3	1.13	21.20
68	10.1	17.7	308.0	49.8	1.07	21.41
69	9.6	17.5	275.0	54.1	1.16	21.45
70	9.5	17.9	247.0	53.5	1.12	21.04
Mean	9.70	18.11	271.00	52.48	1.110	21.153
SD	0.37	1.31	22.32	1.47	0.028	0.239
N	9	9	9	10	10	10

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
91	9.4	14.5	254.0	54.8	1.10	20.07
92	10.2	15.2	224.0	55.4	1.10	19.89
93	9.7	14.1	267.0	54.7	1.11	20.23
94	9.7	15.3	277.0	54.4	1.09	20.06
95	9.9	14.5	274.0	55.8	1.14	20.37
96	9.5	14.8	298.0	55.1	1.14	20.63
97	9.5	14.8	266.0	55.3	1.14	20.55
98	9.2	14.1	306.0	56.1	1.14	20.39
99	9.4	13.6	270.0	56.2	1.10	19.64
100	9.1	15.0	278.0	52.9	1.07	20.34
Mean	9.56	14.59	271.40	55.07	1.113	20.217
SD	0.33	0.54	22.57	0.97	0.025	0.305
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
121	9.8	16.8	322.0	51.5	1.08	21.02
122	9.4	17.3	304.0	51.2	1.07	20.90
123	9.4	16.3	293.0	53.9	1.13	20.89
124	9.6	16.3	299.0	53.1	1.10	20.78
125	8.8	17.9	320.0	52.0	1.10	21.10
126	9.9	16.2	319.0	50.1	1.09	21.83
127	9.7	17.6	298.0	52.1	1.09	20.99
128	9.4	16.5	303.0	50.7	1.06	20.89
129	9.1	18.8	316.0	50.3	1.06	21.06
130	8.2	14.5	326.0	52.0	1.07	20.52
Mean	9.33	16.82	310.00	51.69	1.085	20.998
SD	0.51	1.17	11.81	1.20	0.022	0.336
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
181	9.3	16.9	285.0	50.1	1.05	21.05
182	10.2	17.6	354.0	54.1	1.13	20.94
183	9.5	16.7	354.0	52.0	1.08	20.81
184	9.3	16.5	302.0	53.1	1.12	21.10
185	9.0	16.7	318.0	53.0	1.11	21.02
186	9.5	17.7	339.0	50.4	1.07	21.31
187	9.7	17.9	324.0	49.6	1.05	21.20
188	9.6	17.2	311.0	51.2	1.06	20.73
189	8.5	20.7	362.0	51.9	1.08	20.78
190	9.2	17.0	290.0	51.8	1.07	20.69
Mean	9.38	17.49	323.90	51.72	1.082	20.963
SD	0.45	1.22	27.56	1.43	0.029	0.209
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
161	10.3	14.3	109.0	50.5	1.04	20.69
162	10.0	13.8	104.0	51.4	1.07	20.83
163	9.9	13.8	100.0	49.9	1.04	20.85
164	9.5	16.3	231.0	49.9	1.00	20.12
165	9.1	14.7	160.0	50.4	1.04	20.65
Mean	9.76	14.58	140.80	50.42	1.038	20.628
SD	0.47	1.03	55.98	0.61	0.025	0.297
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
11	9.8	14.9	98.7	49.3	1.01	20.42
12	9.6	14.7	105.0	54.3	1.10	20.27
13	9.2	16.0	281.0	52.6	1.05	19.98
14	9.0	16.4	143.0	51.5	1.04	20.29
15	9.5	16.7	194.0	52.3	1.07	20.44
Mean	9.42	15.74	164.34	52.00	1.054	20.280
SD	0.32	0.90	75.46	1.82	0.034	0.184
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766315

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
41	9.8	16.1	89.4	52.5	1.08	20.49
42	10.4	16.4	87.3	50.7	1.01	20.00
43	10.2	16.3	94.9	51.4	1.05	20.36
44	9.4	14.8	104.0	50.7	1.04	20.48
45	9.9	15.3	102.0	53.1	1.08	20.26
Mean	9.94	15.78	95.52	51.68	1.052	20.318
SD	0.38	0.70	7.40	1.08	0.029	0.201
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766316

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
71	9.8	15.1	99.0	51.9	1.07	20.61
72	9.8	15.0	92.3	49.2	1.02	20.68
73	9.9	15.5	93.8	51.4	1.05	20.39
74	9.4	14.8	98.9	51.2	1.03	20.17
75	9.6	17.8	255.0	51.3	1.03	20.04
Mean	9.70	15.64	127.80	51.00	1.040	20.378
SD	0.20	1.23	71.17	1.04	0.020	0.275
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766317

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
101	9.9	15.2	119.0	49.6	1.02	20.53
102	10.1	14.9	101.0	50.7	1.02	20.08
103	9.9	15.4	91.0	51.1	1.04	20.32
104	9.9	15.5	107.0	50.0	0.99	19.77
105	9.6	15.1	96.5	53.8	1.07	19.83
Mean	9.88	15.22	102.90	51.04	1.028	20.106
SD	0.18	0.24	10.75	1.65	0.029	0.322
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766318

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
131	9.3	20.2	261.0	51.0	1.03	20.23
132	9.3	14.8	117.0	50.5	1.02	20.30
133	10.0	15.6	88.7	48.9	1.01	20.58
134	9.4	16.8	100.0	50.6	1.02	20.14
135	10.0	14.9	97.4	50.1	1.02	20.41
Mean	9.60	16.46	132.82	50.22	1.020	20.332
SD	0.37	2.24	72.39	0.80	0.007	0.170
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766319

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
191	9.0	15.1	102.0	50.3	1.01	20.18
192	9.9	14.6	91.0	49.1	1.00	20.28
193	10.0	14.7	101.0	49.8	1.03	20.73
194	10.0	18.0	93.8	51.0	1.06	20.72
195	9.1	17.1	131.0	50.6	1.02	20.13
Mean	9.60	15.90	103.76	50.16	1.024	20.408
SD	0.50	1.55	15.93	0.74	0.023	0.294
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766320

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
1	7.1	0.69	63.8	12.1	21.0
2	9.7	0.85	81.5	12.3	19.6
3	7.1	0.78	64.2	12.4	20.7
4	8.0	0.72	63.5	13.6	18.5
5	7.4	0.76	70.9	12.8	21.6
11	7.7	0.69	80.0	12.2	21.0
12	8.6	0.97	60.7	12.9	19.0
13	8.2	0.87	76.0	12.4	22.3
14	7.4	0.92	90.6	11.8	22.4
15	7.9	0.65	63.1	12.3	20.8
Mean	7.91	0.790	71.43	12.48	20.69
SD	0.79	0.108	10.12	0.51	1.31
N	10	10	10	10	10

FDA-CBER-2021-5683-0766321

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
31	7.9	1.00	86.8	12.7	22.0
32	7.6	0.90	82.0	13.4	21.8
33	7.5	0.73	97.4	12.8	24.0
34	9.0	0.88	89.8	12.9	22.6
35	8.5	0.94	86.2	13.4	22.0
41	7.6	0.83	90.0	13.5	24.1
42	8.3	0.78	93.5	13.3	23.5
43	9.2	0.82	91.6	13.5	21.1
44	8.9	0.82	90.7	13.6	22.1
45	8.0	0.70	85.7	13.4	24.6
Mean	8.25	0.840	89.37	13.25	22.78
SD	0.63	0.092	4.39	0.32	1.18
N	10	10	10	10	10

FDA-CBER-2021-5683-0766322

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
61	6.9	0.74	78.9	12.0	24.4
62	6.4	0.93	79.6	12.9	23.7
63	8.3	0.81	93.2	12.0	23.2
64	8.2	0.74	80.1	11.2	21.8
65	7.0	0.74	87.1	12.6	24.1
71	8.0	0.98	91.4	11.9	23.8
72	8.0	0.89	91.7	12.4	23.7
73	7.8	0.88	81.4	12.1	22.2
74	7.5	0.77	76.5	11.7	23.3
75	6.2	0.76	79.0	11.8	24.7
Mean	7.43	0.824	83.89	12.06	23.49
SD	0.76	0.089	6.30	0.48	0.91
N	10	10	10	10	10

FDA-CBER-2021-5683-0766323

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
91	8.0	0.72	78.8	12.9	21.8
92	9.1	0.87	67.0	12.2	19.5
93	7.5	0.78	83.7	12.4	21.9
94	8.0	0.96	79.1	12.7	22.2
95	9.1	0.91	76.8	13.0	19.9
101	8.3	0.68	81.8	12.7	23.1
102	7.7	0.94	62.6	13.2	20.4
103	7.4	0.73	74.3	14.0	21.7
104	8.6	0.76	80.8	12.8	20.2
105	7.8	0.79	69.0	12.9	21.4
Mean	8.15	0.814	75.39	12.88	21.21
SD	0.61	0.099	7.01	0.49	1.15
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
121	8.5	0.76	91.9	12.5	25.2
122	7.3	0.82	75.6	12.0	23.4
123	8.1	0.99	72.8	12.3	21.7
124	7.4	0.62	89.9	12.4	25.5
125	7.1	0.87	75.9	11.5	22.6
131	7.2	0.85	79.7	11.8	24.8
132	7.5	0.64	70.0	12.5	23.6
133	8.4	0.89	81.3	11.7	21.6
134	8.2	0.84	92.6	12.4	23.2
135	8.1	0.90	84.6	12.3	22.2
Mean	7.78	0.818	81.43	12.14	23.38
SD	0.53	0.115	8.09	0.36	1.41
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
151	7.8	0.83	91.6	12.6	23.7
152	7.2	0.69	74.9	11.8	23.5
153	8.0	0.81	88.7	12.3	23.5
154	9.1	0.88	85.1	12.3	23.8
155	9.1	1.10	94.1	12.7	24.0
161	7.7	1.00	77.8	12.4	23.0
162	7.2	0.90	81.9	12.1	24.2
163	8.5	0.78	98.2	11.9	23.1
164	7.8	1.00	99.2	12.3	23.2
165	7.4	0.77	89.3	11.7	23.8
Mean	7.98	0.876	88.08	12.21	23.58
SD	0.71	0.126	8.19	0.33	0.39
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
181	8.2	0.69	97.4	12.8	24.1
182	8.1	0.84	76.9	11.8	21.2
183	9.4	0.88	88.3	12.1	25.5
184	8.2	0.69	97.0	12.0	26.0
185	8.1	0.81	95.8	11.8	25.1
191	8.5	0.75	100.5	11.9	24.7
192	9.0	0.63	88.8	12.2	24.4
193	8.6	0.82	76.9	12.2	22.5
194	7.9	1.04	83.7	11.8	22.9
195	8.8	0.88	85.4	11.7	23.2
Mean	8.48	0.803	89.07	12.03	23.96
SD	0.47	0.119	8.48	0.32	1.49
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
151	10.1	0.65	90.3	13.6	21.2
152	10.0 I	0.75 I	99.9 I	12.7 I	23.2 I
153	9.8	0.73	95.5	13.5	21.5
154	10.5	0.72	93.7	13.3	23.1
155	10.2	0.90	93.2	13.2	21.6
156	8.3	0.61	99.3	14.0	24.7
157	10.7	0.62	89.5	13.3	21.1
158	9.3	0.50	88.9	13.0	21.6
159	9.1	0.67	108.8	13.8	24.7
160	7.5	0.58	90.6	12.8	23.4
Mean	9.55	0.673	94.97	13.32	22.61
SD	1.01	0.110	6.21	0.42	1.39
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
1	10.1	1.19	52.1	14.4	18.2
2	12.7	1.01	58.7	15.7	17.2
3	11.2	1.56	54.9	15.6	17.0
4	11.8	1.13	60.6	15.0	16.4
5	10.7	1.35	58.1	16.4	19.1
6	11.3	1.01	55.5	16.1	18.1
7	9.7	1.03	58.5	14.4	19.3
8	10.9	0.96	58.1	15.0	19.3
9	10.3	1.26	53.3	14.7	18.0
10	10.4	1.30	56.1	14.4	18.3
Mean	10.91	1.180	56.59	15.17	18.09
SD	0.88	0.190	2.67	0.74	0.99
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
31	10.9	1.04	62.7	16.0	18.7
32	12.0	1.04	73.6	16.5	19.2
33	10.1	0.72	67.9	16.5	20.9
34	12.8	0.99	73.3	16.4	20.3
35	11.1	1.14	67.9	16.8	19.7
36	12.4	1.06	65.5	17.3	19.0
37	12.2	0.98	72.7	15.6	19.6
38	12.2	0.78	82.6	15.8	21.0
39	12.9	0.68	78.1	15.6	20.2
40	11.3	0.98	64.5	16.2	18.7
Mean	11.79	0.941	70.88	16.27	19.73
SD	0.90	0.157	6.33	0.54	0.85
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
61	9.4	0.66	81.8	13.6	19.9
62	7.5	0.92	84.8	13.8	21.8
63	10.1	0.68	86.3	13.3	19.9
64	8.9	0.68	86.1	13.0	21.3
65	8.1	0.70	77.4	14.4	21.4
66	9.2	0.58	87.7	12.0	20.1
67	8.6	0.59	92.8	13.2	23.1
68	8.0	0.66	94.4	13.3	22.9
69	7.9	0.67	82.4	13.5	21.3
70	9.1	0.76	75.0	13.1	20.4
Mean	8.68	0.690	84.87	13.32	21.21
SD	0.81	0.096	6.09	0.62	1.16
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
91	11.4	1.00	63.2	17.1	19.4
92	12.3	1.08	57.3	16.9	18.4
93	11.8	1.04	61.0	17.2	17.7
94	11.4	1.50	56.6	17.2	18.5
95	12.6	1.12	60.9	17.1	17.9
96	10.0	0.91	65.7	15.2	20.2
97	11.7	1.25	62.2	15.8	17.9
98	11.9	0.95	60.7	17.0	18.1
99	12.1	0.85	61.4	15.6	19.4
100	10.3	1.02	65.0	16.1	18.9
Mean	11.55	1.072	61.40	16.52	18.64
SD	0.83	0.188	2.91	0.76	0.82
N	10	10	10	10	10

FDA-CBER-2021-5683-0766332

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
121	10.0	0.63	88.2	13.4	22.5
122	9.2	0.61	89.6	13.9	21.8
123	8.6	0.88	76.7	14.7	21.1
124	8.4	0.80	78.1	13.7	21.4
125	8.5	0.75	81.7	12.7	20.2
126	10.2	0.75	89.3	13.0	22.4
127	8.3	0.82	86.3	12.6	23.0
128	9.7	0.69	77.3	13.4	20.5
129	8.8	0.61	76.2	12.6	21.2
130	8.7	0.79	88.8	13.2	22.0
Mean	9.04	0.733	83.22	13.32	21.61
SD	0.69	0.094	5.76	0.66	0.90
N	10	10	10	10	10

FDA-CBER-2021-5683-0766333

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
181	8.9	0.67	80.8	13.5	21.0
182	8.5	0.68	78.6	13.3	20.9
183	10.4	0.68	85.7	13.6	23.2
184	9.9	0.73	86.3	12.8	22.7
185	9.9	0.73	84.9	12.7	21.8
186	8.9	0.52	81.4	13.5	21.7
187	8.6	0.73	85.1	12.4	21.1
188	10.0	1.02	81.3	14.4	20.3
189	9.5	0.69	76.5	13.4	20.1
190	9.0	0.78	84.6	13.9	22.0
Mean	9.36	0.723	82.52	13.35	21.48
SD	0.66	0.125	3.31	0.59	0.99
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
161	8.4	0.86	68.4	13.8	20.2
162	8.3	0.92	67.0	12.7	19.5
163	7.2	0.62	81.8	12.8	22.1
164	7.8	0.66	67.5	13.0	19.4
165	8.0	0.83	66.1	12.9	19.9
Mean	7.94	0.778	70.16	13.04	20.22
SD	0.48	0.131	6.56	0.44	1.10
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
11	8.2	0.95	65.2	11.1	19.0
12	9.6	0.90	69.9	11.8	18.2
13	9.6	0.94	67.0	12.5	18.7
14	7.7	0.85	72.5	11.4	20.3
15	9.2	0.69	67.3	10.7	18.3
Mean	8.86	0.866	68.38	11.50	18.90
SD	0.86	0.106	2.85	0.69	0.85
N	5	5	5	5	5

FDA-CBER-2021-5683-0766336

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
41	8.5	0.94	62.6	13.7	17.9
42	8.2	0.96	71.8	13.8	19.3
43	7.7	0.90	63.8	13.2	19.5
44	7.7	0.78	70.1	13.1	21.0
45	8.6	0.93	70.2	13.9	20.1
Mean	8.14	0.902	67.70	13.54	19.56
SD	0.43	0.072	4.18	0.36	1.14
N	5	5	5	5	5

FDA-CBER-2021-5683-0766337

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
71	7.8	0.96	68.6	13.6	20.6
72	8.2	0.72	84.7	13.3	21.6
73	8.7	0.71	74.8	13.4	18.8
74	8.0	0.91	62.2	13.9	20.1
75	7.3	0.85	61.8	14.1	20.6
Mean	8.00	0.830	70.42	13.66	20.34
SD	0.51	0.112	9.60	0.34	1.02
N	5	5	5	5	5

FDA-CBER-2021-5683-0766338

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
101	9.6	0.88	66.0	13.2	19.2
102	8.2	0.71	74.1	13.4	19.9
103	7.2	0.78	68.6	13.3	21.4
104	8.9	0.70	77.9	12.9	18.7
105	8.3	0.86	58.8	14.4	18.9
Mean	8.44	0.786	69.08	13.44	19.62
SD	0.89	0.083	7.39	0.57	1.09
N	5	5	5	5	5

FDA-CBER-2021-5683-0766339

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
131	8.3	0.83	60.5	12.7	18.4
132	9.5	0.78	79.4	13.6	18.8
133	7.0	0.69	76.3	13.4	22.2
134	8.2	0.76	69.5	13.8	18.9
135	9.3	0.81	80.9	13.2	19.2
Mean	8.46	0.774	73.32	13.34	19.50
SD	1.00	0.054	8.40	0.42	1.54
N	5	5	5	5	5

FDA-CBER-2021-5683-0766340

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
191	8.0	0.74	70.9	12.8	19.5
192	8.3	0.92	77.1	13.6	21.1
193	7.8	0.85	62.6	14.0	20.9
194	8.4	1.03	74.8	12.8	18.5
195	8.3	0.67	60.9	13.1	19.0
Mean	8.16	0.842	69.26	13.26	19.80
SD	0.25	0.143	7.23	0.53	1.15
N	5	5	5	5	5

FDA-CBER-2021-5683-0766341

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
16	8.0	7.01	4.85	3.3	230.3	867	37.2
17	9.0	7.70	6.03	2.5	193.1	970	42.6
18	9.2	7.67	8.81	1.8	139.2	876	43.9
19	9.1	7.83	14.85	2.2	171.5	972	43.3
20	8.8	7.37	8.34	2.5	182.1	820	40.9
26	9.2	7.74	13.53	2.4	187.4	874	43.2
27	9.2	7.80	7.30	3.3	257.5	1063	44.0
28	8.1	7.28	7.29	2.5	182.9	858	38.1
29	9.3	7.97	6.77	2.3	185.1	1248	43.9
30	8.8	8.17	6.40	2.8	227.8	1203	41.6
Mean	8.87	7.654	8.417	2.56	195.69	975.1	41.87
SD	0.46	0.344	3.256	0.47	33.93	150.4	2.45
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766342

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
46	8.4	7.09	11.13	1.7	117.1	628	39.9
47	9.4	8.02	11.27	0.6	45.4	830	44.0
48	8.5	7.12	15.33	1.2	83.2	1021	40.5
49	8.6	7.59	13.35	1.0	72.1	566	41.0
50	8.4	7.13	11.88	1.1	78.8	606	39.0
56	8.7	7.32	14.90	0.5	39.5	743	41.3
57	8.6	7.39	11.66	0.6	45.8	828	40.0
58	8.1	6.83	12.25	1.2	82.4	726	38.0
59	8.8	7.40	12.00	0.8	60.0	789	41.5
60	8.2	7.06	15.16	1.0	73.2	799	38.9
Mean	8.57	7.295	12.893	0.97	69.75	753.6	40.41
SD	0.36	0.334	1.660	0.36	23.24	133.3	1.69
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
76	9.7	8.47	9.12	1.4	118.0	1436	44.8
77	8.9	7.77	8.21	1.1	83.9	1061	41.6
78	9.2	7.55	12.17	1.3	95.1	1292	42.4
79	8.3	6.99	3.92	2.0	141.2	715	37.6
80	9.3	8.09	6.64	0.8	61.7	1070	43.3
86	9.3	8.19	7.21	0.8	67.4	868	42.5
87	9.0	7.66	11.75	1.4	104.2	1427	43.0
88	9.2	7.95	10.58	1.1	90.4	956	42.8
89	9.3	7.84	8.74	1.3	101.1	916	43.1
90	9.0	7.56	8.85	1.1	85.8	942	41.2
Mean	9.12	7.807	8.719	1.23	94.88	1068.3	42.23
SD	0.36	0.409	2.464	0.35	23.30	242.8	1.90
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
106	8.2	6.76	8.15	1.8	121.9	1091	39.2
107	8.9	7.87	6.56	2.0	156.0	919	42.7
108	8.6	7.52	8.43	1.1	84.9	945	40.8
109	8.6	6.99	8.57	2.1	146.8	1264	40.6
110	8.8	7.46	8.05	0.9	67.1	1051	42.2
116	8.8	7.47	7.41	1.9	143.2	1004	42.0
117	9.0	8.14	9.15	2.4	191.7	820	43.5
118	8.4	7.41	12.45	2.8	204.7	862	39.9
119	8.4	7.19	5.42	1.9	133.0	903	38.9
120	9.3	8.25	8.92	2.3	189.2	998	44.1
Mean	8.70	7.506	8.311	1.92	143.85	985.7	41.39
SD	0.33	0.474	1.844	0.57	44.93	128.7	1.79
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
136	8.2	7.71	7.28	1.6	124.4	873	39.7
137	8.5	7.40	10.51	1.1	81.7	1097	40.1
138	8.1	7.14	5.71	1.6	116.1	970	37.3
139	8.9	7.94	9.56	1.7	137.0	1153	42.0
140	8.9	7.66	11.59	1.2	93.8	972	41.3
146	8.6	7.69	8.20	1.5	118.9	856	40.9
147	9.1	7.85	9.79	1.1	89.8	1202	42.9
148	8.8	7.21	8.87	1.7	120.1	1063	41.1
149	8.5	7.57	7.90	1.9	144.6	1201	39.6
150	8.6	7.72	11.08	1.3	96.9	1099	40.0
Mean	8.62	7.589	9.049	1.47	112.33	1048.6	40.49
SD	0.32	0.262	1.822	0.28	20.92	125.9	1.54
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
166	8.3	7.02	8.18	1.2	86.9	908	37.6
167	9.0	7.35	15.37	1.3	93.9	811	41.2
168	8.9	7.99	7.10	0.9	69.6	1163	41.0
169	8.5	7.51	8.12	1.0	77.8	1230	39.4
170	9.3	8.01	12.32	0.7	56.4	914	41.7
176	9.1	7.79	11.53	1.0	76.4	978	42.0
177	8.2	7.39	6.95	1.0	76.8	1038	38.1
178	8.6	7.43	11.38	1.0	72.7	808	40.2
179	8.9	7.32	11.92	1.1	83.9	1141	41.0
180	9.0	7.95	7.42	1.3	101.9	1011	40.9
Mean	8.78	7.576	10.029	1.05	79.63	1000.2	40.31
SD	0.36	0.339	2.855	0.18	12.83	145.2	1.49
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
196	8.3	7.17	11.38	1.5	106.8	959	38.3
197	8.6	7.35	10.95	1.2	90.0	990	39.8
198	9.0	8.09	9.43	1.7	133.7	923	41.9
199	8.9	7.54	9.26	0.8	63.3	1020	41.8
200	8.2	7.23	6.17	1.0	69.4	965	37.5
206	9.3	7.15	10.28	1.2	87.5	878	37.8
207	9.1	8.05	9.67	1.3	101.6	1025	42.7
208	8.8	8.31	17.63	1.9	154.7	970	41.0
209	8.7	7.73	9.04	1.6	122.5	1261	40.6
210	8.5	7.16	10.14	1.2	83.6	1174	40.1
Mean	8.74	7.578	10.395	1.34	101.31	1016.5	40.15
SD	0.35	0.440	2.908	0.33	28.82	116.2	1.80
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
166	7.9	6.67	11.87	3.2	213.1	561	36.0
167	8.3	6.97	18.90	2.8	192.9	542	38.4
168	8.5	7.82	13.17	2.2	168.5	656	39.5
169	8.0	7.07	11.62	3.7	258.2	774	37.2
170	8.5	7.52	17.21	2.3	176.5	574	39.0
171	8.8	7.75	15.70	1.4	109.9	499	40.5
172	8.6	7.36	14.23	2.9	212.6	291	39.5
173	9.0	8.47	17.48	1.5	127.0	462	41.3
174	8.3	7.34	17.15	2.3	170.0	561	37.9
175	8.4	7.22	15.34	3.0	215.7	784	39.3
Mean	8.43	7.419	15.267	2.53	184.44	570.4	38.86
SD	0.33	0.508	2.493	0.73	44.08	145.4	1.55
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
16	8.6	7.60	4.34	2.7	201.5	968	41.1
17	9.6	8.16	4.50	1.7	138.8	1259	45.5
18	9.3	8.01	5.88	2.9	228.3	923	45.5
19	9.0	7.86	11.29	2.7	213.6	1098	42.8
20	9.3	8.04	10.39	2.2	176.0	883	44.0
21	8.7	7.51	6.73	2.9	219.1	927	42.1
22	8.6	7.84	5.54	2.1	164.0	1168	40.6
23	9.2	8.03	8.06	2.2	179.4	1032	44.6
24	9.5	8.08	8.70	2.6	210.8	1177	45.4
25	9.0	7.79	5.63	3.6	278.0	1246	42.9
Mean	9.08	7.892	7.106	2.56	200.95	1068.1	43.45
SD	0.36	0.213	2.414	0.53	38.85	140.4	1.83
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
46	8.3	7.16	12.57	2.5	180.3	460	39.5
47	9.4	8.20	10.21	1.7	136.8	520	45.7
48	8.8	7.51	23.55	2.2	165.8	912	42.8
49	8.5	7.38	8.62	3.6	266.9	397	41.1
50	8.6	7.52	13.64	3.4	258.3	524	41.9
51	8.5	7.55	16.49	2.8	214.1	674	40.7
52	8.7	7.64	17.05	3.6	273.9	623	42.4
53	8.7	7.55	15.06	2.5	191.0	795	41.8
54	8.9	7.93	14.77	1.9	154.3	668	42.7
55	8.2	7.02	13.04	2.2	156.3	656	38.8
Mean	8.66	7.546	14.500	2.64	199.77	622.9	41.74
SD	0.34	0.340	4.114	0.69	50.73	155.2	1.92
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
76	8.7	7.90	13.75	3.7	290.4	932	41.8
77	8.2	7.31	10.64	3.1	223.4	855	39.5
78	8.7	7.34	11.29	3.2	231.9	892	40.6
79	8.1	6.94	8.40	4.8	329.7	482	38.1
80	8.3	7.50	11.18	2.0	147.6	633	38.9
81	8.6	7.52	7.18	2.1	156.6	580	40.1
82	8.5	7.66	8.50	3.8	290.7	846	39.2
83	8.6	7.87	14.44	3.3	259.2	588	39.4
84	8.4	7.44	10.86	2.3	172.6	521	38.9
85	7.7	7.17	13.92	2.1	153.3	652	35.9
Mean	8.38	7.465	11.016	3.04	225.54	698.1	39.24
SD	0.32	0.298	2.490	0.92	66.10	166.4	1.56
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
106	7.8	6.63	13.41	3.3	220.8	1022	38.1
107	8.2	7.43	9.89	2.7	198.4	803	39.5
108	8.2	7.43	15.17	2.3	174.4	924	40.1
109	8.6	7.20	13.13	4.1	297.7	939	41.9
110	8.0	6.93	14.87	3.6	248.3	986	38.7
111	8.3	7.59	16.75	2.4	185.2	880	40.0
112	7.6	7.18	6.20	2.9	211.3	825	37.2
113	7.9	7.20	8.53	2.8	203.1	603	39.0
114	8.0	7.31	17.51	2.5	184.9	875	39.0
115	8.7	7.58	11.98	2.3	174.8	911	41.5
Mean	8.13	7.248	12.744	2.89	209.89	876.8	39.50
SD	0.34	0.296	3.637	0.60	38.31	117.1	1.44
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
136	7.2	6.86	13.94	3.8	260.7	805	34.2
137	8.3	7.60	20.24	2.7	205.1	723	39.7
138	7.2	6.61	12.05	4.1	273.1	750	34.5
139	7.8	7.20	16.30	3.3	239.8	555	37.6
140	8.0	7.16	14.54	2.6	186.8	586	38.2
141	8.0	7.51	11.51	2.9	215.6	815	37.2
142	8.8	7.68	11.99	2.6	202.0	600	41.4
143	7.8	6.97	15.11	4.4	308.7	553	36.4
144	8.0	7.02	15.70	2.4	169.7	849	37.2
145	7.4	6.84	12.67	3.0	205.1	786	34.2
Mean	7.85	7.145	14.405	3.18	226.66	702.2	37.06
SD	0.50	0.355	2.642	0.70	43.09	116.6	2.38
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
196	7.3	6.55	16.58	3.8	250.1	792	34.7
197	7.8	6.89	13.40	2.3	160.0	765	37.2
198	8.2	7.59	18.97	2.3	176.1	812	39.7
199	8.3	7.28	15.22	1.9	137.8	658	39.2
200	7.6	6.97	14.01	3.2	220.8	663	35.3
201	8.4	7.23	16.37	3.0	219.3	752	39.4
202	8.2	7.36	12.99	2.8	207.6	596	39.5
203	8.0	7.21	15.39	2.3	166.0	759	37.6
204	7.7	6.97	19.03	2.9	204.6	889	36.9
205	7.8	7.10	8.01	3.3	237.2	358	36.4
Mean	7.93	7.115	14.997	2.78	197.95	704.4	37.59
SD	0.35	0.288	3.215	0.58	36.41	148.3	1.81
N	10	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
176	8.6	7.87	5.63	3.8	300.6	1209	41.6
177	8.8	8.27	5.16	2.3	189.7	998	41.7
178	8.9	8.22	4.61	3.3	268.0	839	42.6
179	8.8	7.73	8.04	3.3	258.3	988	40.9
180	9.1	8.62	4.13	2.6	224.9	1095	43.8
Mean	8.84	8.142	5.514	3.06	248.30	1025.8	42.12
SD	0.18	0.352	1.521	0.60	42.44	137.3	1.12
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
26	8.8	8.10	8.20	2.6	210.9	992	42.8
27	9.1	8.06	5.64	3.3	265.2	1005	44.0
28	8.3	7.89	6.69	4.4	344.9	514	40.0
29	9.0	8.34	5.29	3.2	268.6	1242	43.6
30	8.8	8.49	4.60	2.5	209.8	996	42.1
Mean	8.80	8.176	6.084	3.20	259.88	949.8	42.50
SD	0.31	0.238	1.403	0.76	55.32	265.6	1.58
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
56	9.2	8.35	7.57	2.1	177.2	1130	45.3
57	8.6	7.87	7.46	2.4	192.2	932	41.4
58	8.1	7.48	7.81	3.5	264.1	1014	40.2
59	8.6	7.55	3.40	4.7	355.9	828	42.2
60	8.8	8.30	11.87	2.3	192.6	798	42.6
Mean	8.66	7.910	7.622	3.00	236.40	940.4	42.34
SD	0.40	0.407	2.997	1.10	74.87	136.3	1.89
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
86	9.2	8.74	7.03	2.8	246.6	999	44.0
87	8.7	7.99	10.04	2.6	209.7	1319	42.2
88	9.1	8.31	7.97	2.3	187.7	882	44.4
89	8.9	8.04	5.57	1.8	145.6	946	43.2
90	9.3	8.48	4.45	1.9	158.1	818	44.4
Mean	9.04	8.312	7.012	2.28	189.54	992.8	43.64
SD	0.24	0.312	2.164	0.43	40.57	194.6	0.94
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
116	9.1	8.35	4.58	3.0	246.8	830	44.0
117	8.9	8.72	8.45	2.6	227.5	840	43.5
118	8.8	8.62	11.45	2.4	207.6	932	43.2
119	8.6	7.73	4.17	2.8	214.6	760	40.9
120	9.6	9.37	7.76	2.1	200.6	763	46.9
Mean	9.00	8.558	7.282	2.58	219.42	825.0	43.70
SD	0.38	0.595	2.998	0.35	18.25	70.3	2.15
N	5	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
146	8.8	8.46	7.57	1.0	88.6	721	43.0
147	8.3	7.52	4.92	3.4	255.9	1087	40.8
148	8.7	7.86	5.53	2.4	189.1	800	42.4
149	8.5	8.16	10.05	2.3	187.0	906	40.8
150	9.2	8.61	6.08	2.5	216.2	943	44.6
Mean	8.70	8.122	6.830	2.32	187.36	891.4	42.32
SD	0.34	0.443	2.050	0.86	61.82	140.1	1.60
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766361

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters						
	HGB (mmol/L)	RBC (x10E6/µL)	WBC (x10E3/µL)	Reti (%)	Reti (x10E3/µL)	PLT (x10E3/µL)	HCT (%)
206	9.2	8.79	6.31	1.8	158.9	797	45.0
207	8.8	8.18	8.87	1.8	144.1	942	42.5
208	8.9	9.02	9.69	2.4	217.1	1040	43.7
209	8.8	8.12	3.56	2.3	189.9	1068	42.8
210	9.1	8.12	7.17	3.0	241.4	1145	43.8
Mean	8.96	8.446	7.120	2.26	190.28	998.4	43.56
SD	0.18	0.428	2.398	0.50	40.16	134.0	0.98
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766362

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
16	14.3	80.9	2.5	1.6	0.5	0.2
17	27.4	64.5	3.8	3.3	0.9	0.2
18	16.0	79.4	2.4	1.0	0.9	0.3
19	7.6	87.3	2.1	1.0	1.5	0.5
20	6.8	88.8	1.4	1.5	1.1	0.3
26	7.7	87.7	1.8	1.4	1.2	0.3
27	19.4	75.3	2.7	1.3	1.0	0.2
28	15.8	80.2	1.9	1.2	0.8	0.2
29	15.8	76.4	3.3	3.4	0.7	0.4
30	15.5	80.6	1.6	1.1	0.9	0.2
Mean	14.63	80.11	2.35	1.68	0.95	0.28
SD	6.24	7.20	0.76	0.90	0.28	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
46	28.7	61.5	3.3	1.5	4.6	0.4
47	23.9	63.8	3.0	0.9	7.9	0.4
48	28.8	63.0	3.9	0.8	3.0	0.4
49	32.1	57.4	2.9	1.3	5.7	0.5
50	29.3	63.0	3.0	1.7	2.5	0.5
56	34.1	55.2	2.4	1.2	6.7	0.5
57	30.7	62.0	2.5	2.2	2.1	0.5
58	35.1	55.7	2.9	1.0	4.9	0.3
59	24.9	63.5	4.6	1.9	4.6	0.5
60	28.8	60.8	5.0	1.3	3.6	0.5
Mean	29.64	60.59	3.35	1.38	4.56	0.45
SD	3.57	3.27	0.87	0.45	1.85	0.07
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
76	13.3	78.7	2.9	1.7	2.9	0.3
77	12.7	80.6	2.9	1.8	1.7	0.3
78	11.2	82.1	2.6	0.9	2.6	0.5
79	12.4	79.3	3.8	1.4	2.9	0.2
80	15.3	77.2	3.3	1.8	2.1	0.4
86	10.6	84.9	1.6	1.1	1.4	0.4
87	7.1	87.9	2.1	0.7	1.7	0.5
88	13.7	80.8	2.8	1.0	1.3	0.4
89	12.1	82.2	2.0	0.8	2.5	0.4
90	21.2	71.6	3.1	1.3	2.5	0.3
Mean	12.96	80.53	2.71	1.25	2.16	0.37
SD	3.62	4.40	0.66	0.41	0.60	0.09
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
106	13.1	81.0	2.4	1.4	1.6	0.4
107	10.0	83.3	1.6	4.0	0.8	0.3
108	18.5	75.9	2.8	1.0	1.5	0.4
109	11.2	81.5	2.4	3.0	1.5	0.4
110	13.4	81.3	2.4	1.3	1.4	0.2
116	11.2	83.9	1.8	1.7	1.1	0.3
117	12.6	82.5	1.7	1.6	1.2	0.4
118	11.9	82.2	2.4	1.7	1.3	0.5
119	14.3	80.2	2.3	1.7	1.2	0.2
120	18.9	75.6	1.9	2.0	1.2	0.4
Mean	13.51	80.74	2.17	1.94	1.28	0.35
SD	3.00	2.85	0.39	0.90	0.23	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
136	12.9	81.6	2.2	0.7	2.1	0.4
137	18.8	75.0	2.0	2.1	1.8	0.3
138	13.8	82.4	1.3	1.0	1.1	0.3
139	15.6	79.2	1.8	1.0	2.0	0.3
140	32.2	60.7	2.1	0.8	3.8	0.3
146	11.2	82.0	2.7	1.3	2.4	0.4
147	15.5	78.2	3.0	0.9	2.0	0.5
148	15.8	77.0	3.1	1.0	2.9	0.2
149	12.6	79.1	1.6	1.7	4.6	0.4
150	32.3	54.6	2.4	1.1	9.1	0.5
Mean	18.07	74.98	2.22	1.16	3.18	0.36
SD	7.76	9.53	0.59	0.43	2.32	0.10
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
166	24.3	66.5	4.0	0.9	3.9	0.3
167	19.8	72.2	4.0	1.0	2.5	0.5
168	29.3	61.3	2.7	1.7	4.5	0.5
169	19.6	71.9	4.1	1.3	2.7	0.5
170	24.0	69.1	3.2	1.1	2.1	0.4
176	26.1	64.1	2.7	0.9	5.7	0.6
177	22.4	67.7	3.4	3.1	3.0	0.4
178	23.6	68.4	2.9	1.6	3.1	0.3
179	19.9	70.6	4.4	1.2	3.3	0.6
180	20.4	69.0	5.4	1.7	3.1	0.3
Mean	22.94	68.08	3.68	1.45	3.39	0.44
SD	3.18	3.41	0.86	0.66	1.06	0.12
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
196	19.0	76.1	1.8	0.9	1.7	0.5
197	26.7	62.5	2.7	1.5	6.1	0.4
198	18.7	76.6	1.2	1.4	1.8	0.3
199	12.6	80.9	2.0	1.6	2.6	0.4
200	28.8	61.1	3.9	2.5	3.5	0.2
206	28.8	65.6	2.1	1.0	2.2	0.4
207	26.3	66.0	2.0	1.2	4.2	0.4
208	32.8	59.1	2.1	1.8	3.7	0.4
209	20.3	71.9	1.7	2.8	2.9	0.4
210	22.7	67.2	2.5	1.1	6.0	0.5
Mean	23.67	68.70	2.20	1.58	3.47	0.39
SD	6.09	7.33	0.73	0.63	1.58	0.09
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766369

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
166	39.8	52.0	1.8	0.8	5.3	0.3
167	36.2	56.0	2.5	0.8	4.2	0.4
168	45.8	44.6	3.1	0.7	5.3	0.4
169	41.0	48.7	2.4	0.4	7.2	0.3
170	46.0	45.7	2.3	0.6	5.0	0.4
171	47.5	41.0	3.5	0.6	7.0	0.3
172	54.1	36.8	2.1	0.5	6.1	0.4
173	32.2	58.7	1.5	0.2	6.8	0.6
174	39.4	50.7	2.5	0.4	6.7	0.4
175	50.3	41.2	3.6	0.9	3.8	0.2
Mean	43.23	47.54	2.53	0.59	5.74	0.37
SD	6.69	6.97	0.69	0.22	1.20	0.11
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766370

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
16	20.6	74.4	3.2	1.0	0.7	0.1
17	28.3	65.1	3.6	2.2	0.6	0.2
18	13.7	82.1	1.6	1.3	0.9	0.3
19	11.5	83.1	2.2	1.8	1.1	0.3
20	7.9	86.6	2.5	1.2	1.4	0.3
21	9.7	85.6	2.3	1.0	1.2	0.2
22	13.0	81.7	3.0	1.1	1.0	0.1
23	11.0	83.4	2.7	1.1	1.6	0.2
24	13.9	80.3	3.3	1.1	1.0	0.3
25	15.9	79.6	2.7	1.0	0.5	0.3
Mean	14.55	80.19	2.71	1.28	1.00	0.23
SD	5.97	6.30	0.59	0.40	0.35	0.08
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766371

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
46	34.9	57.9	1.5	0.7	4.5	0.4
47	42.2	52.5	1.2	0.8	2.6	0.6
48	53.4	34.6	4.0	0.5	7.0	0.6
49	39.0	52.4	2.1	0.6	5.5	0.4
50	55.2	38.6	1.9	0.9	3.1	0.3
51	34.4	54.8	2.6	0.5	7.2	0.5
52	43.8	42.0	3.2	0.8	9.8	0.4
53	45.7	42.9	2.7	0.5	7.9	0.4
54	43.4	48.3	2.7	1.0	4.2	0.3
55	50.3	41.9	2.1	0.8	4.7	0.3
Mean	44.23	46.59	2.40	0.71	5.65	0.42
SD	7.15	7.68	0.82	0.18	2.28	0.11
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
76	39.6	48.9	5.3	1.5	4.4	0.2
77	36.1	57.1	4.1	0.9	1.5	0.2
78	36.4	53.4	3.4	1.4	5.1	0.4
79	35.1	55.9	4.6	1.1	3.2	0.3
80	43.0	48.4	4.2	0.9	3.1	0.4
81	45.4	45.2	4.6	1.2	3.2	0.4
82	45.0	44.1	3.5	4.5	2.4	0.5
83	37.3	50.8	3.0	0.9	7.6	0.4
84	33.0	51.6	4.6	1.3	9.0	0.5
85	30.0	63.5	3.0	0.9	2.3	0.4
Mean	38.09	51.89	4.03	1.46	4.18	0.37
SD	5.11	5.85	0.78	1.09	2.42	0.11
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
106	32.6	58.5	3.1	1.7	3.8	0.3
107	25.8	65.3	2.8	3.8	2.0	0.3
108	57.5	32.3	3.0	1.8	5.1	0.3
109	35.9	54.3	4.2	2.5	2.7	0.4
110	48.2	42.0	3.2	1.8	4.6	0.3
111	43.0	44.7	5.3	2.8	3.8	0.4
112	46.2	45.0	3.4	2.8	2.4	0.2
113	42.6	47.2	3.9	2.6	3.4	0.3
114	44.8	48.1	2.5	2.0	2.2	0.4
115	52.9	37.8	3.5	3.2	2.4	0.3
Mean	42.95	47.52	3.49	2.50	3.24	0.32
SD	9.45	9.74	0.81	0.69	1.07	0.06
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766374

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
136	50.7	39.4	2.7	2.3	4.6	0.3
137	54.0	32.1	3.4	3.6	6.6	0.4
138	38.5	51.9	3.3	4.2	1.9	0.2
139	44.6	46.5	3.2	3.3	2.1	0.3
140	46.4	40.1	2.9	3.4	6.8	0.4
141	58.9	30.3	2.9	4.4	3.3	0.2
142	47.5	45.0	3.1	1.6	2.5	0.4
143	45.8	45.3	1.2	3.8	3.5	0.3
144	52.1	35.2	2.5	4.1	5.9	0.3
145	42.0	45.5	3.0	4.5	4.8	0.2
Mean	48.05	41.13	2.82	3.52	4.20	0.30
SD	6.00	6.95	0.63	0.93	1.82	0.08
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766375

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
196	45.0	43.5	2.0	3.6	5.6	0.2
197	44.9	46.1	1.3	3.5	4.0	0.3
198	60.0	31.3	2.7	3.4	2.3	0.3
199	49.3	39.5	2.3	4.2	4.4	0.3
200	59.3	29.6	2.2	4.0	4.7	0.2
201	60.0	31.5	0.9	4.1	3.1	0.3
202	44.0	44.6	1.7	6.2	3.1	0.3
203	43.2	47.6	2.6	2.3	4.2	0.2
204	39.1	52.1	2.6	3.9	2.1	0.3
205	42.2	50.7	1.8	2.8	2.4	0.2
Mean	48.70	41.65	2.01	3.80	3.59	0.26
SD	8.05	8.29	0.59	1.03	1.17	0.05
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766376

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
176	11.2	83.9	2.1	1.5	1.0	0.3
177	18.5	75.2	2.6	2.9	0.5	0.3
178	10.4	84.1	2.7	1.4	1.3	0.2
179	16.6	76.9	4.0	1.4	0.9	0.3
180	14.9	78.7	2.5	2.8	1.0	0.1
Mean	14.32	79.76	2.78	2.00	0.94	0.24
SD	3.47	4.06	0.72	0.78	0.29	0.09
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766377

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
26	11.6	83.8	2.7	0.8	1.0	0.2
27	21.6	71.6	2.2	3.8	0.6	0.2
28	16.4	76.6	3.8	1.5	1.4	0.3
29	18.9	70.6	3.6	6.0	0.8	0.2
30	9.4	82.7	3.3	3.2	1.1	0.3
Mean	15.58	77.06	3.12	3.06	0.98	0.24
SD	5.05	6.10	0.66	2.05	0.30	0.05
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
56	15.7	78.4	2.8	1.6	1.1	0.4
57	14.2	80.3	1.7	2.3	1.3	0.2
58	12.9	81.4	2.9	1.1	1.6	0.2
59	20.2	75.3	2.0	1.5	0.8	0.2
60	16.4	77.9	3.2	1.4	0.8	0.3
Mean	15.88	78.66	2.52	1.58	1.12	0.26
SD	2.77	2.35	0.64	0.44	0.34	0.09
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
86	12.4	83.0	2.4	0.9	1.2	0.1
87	11.2	82.9	3.4	1.0	1.2	0.3
88	17.0	75.3	4.0	2.2	1.2	0.3
89	15.4	80.1	2.4	1.1	0.8	0.3
90	18.8	72.0	3.4	5.1	0.6	0.1
Mean	14.96	78.66	3.12	2.06	1.00	0.22
SD	3.15	4.86	0.70	1.78	0.28	0.11
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
116	26.8	64.9	2.3	5.1	0.7	0.2
117	17.6	76.0	3.3	1.3	1.5	0.2
118	13.6	80.0	2.7	2.1	1.3	0.3
119	18.6	74.4	3.7	1.9	1.3	0.1
120	16.5	77.7	3.2	1.7	0.7	0.3
Mean	18.62	74.60	3.04	2.42	1.10	0.22
SD	4.94	5.81	0.55	1.53	0.37	0.08
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766381

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
146	14.6	79.0	3.6	1.7	0.8	0.3
147	21.3	72.9	3.7	1.2	0.8	0.1
148	24.0	70.5	2.8	1.6	1.0	0.1
149	10.7	84.2	2.3	1.6	1.0	0.2
150	20.4	73.0	3.7	1.4	1.2	0.2
Mean	18.20	75.92	3.22	1.50	0.96	0.18
SD	5.42	5.59	0.64	0.20	0.17	0.08
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766382

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (%)	Lym (%)	Mono (%)	Eos (%)	LUC (%)	Baso (%)
206	19.2	74.0	2.3	3.2	1.1	0.2
207	16.3	78.3	2.4	1.6	1.1	0.3
208	12.1	82.7	2.6	1.5	0.9	0.2
209	18.9	75.6	2.8	1.8	0.7	0.2
210	22.5	72.4	1.9	2.1	0.8	0.4
Mean	17.80	76.60	2.40	2.04	0.92	0.26
SD	3.87	4.05	0.34	0.69	0.18	0.09
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
16	0.69	3.93	0.12	0.08	0.03	0.01
17	1.65	3.89	0.23	0.20	0.05	0.01
18	1.41	7.00	0.21	0.09	0.08	0.03
19	1.13	12.96	0.31	0.15	0.22	0.07
20	0.57	7.41	0.12	0.13	0.09	0.03
26	1.04	11.86	0.24	0.20	0.16	0.04
27	1.42	5.50	0.20	0.10	0.07	0.02
28	1.15	5.84	0.14	0.09	0.06	0.01
29	1.07	5.17	0.23	0.23	0.05	0.02
30	0.99	5.16	0.10	0.07	0.06	0.02
Mean	1.112	6.872	0.190	0.134	0.087	0.026
SD	0.328	3.137	0.067	0.058	0.059	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
46	3.19	6.85	0.37	0.16	0.52	0.04
47	2.69	7.19	0.34	0.10	0.89	0.05
48	4.42	9.66	0.60	0.13	0.45	0.07
49	4.28	7.67	0.39	0.18	0.76	0.07
50	3.48	7.49	0.35	0.20	0.30	0.06
56	5.08	8.22	0.35	0.17	1.00	0.07
57	3.58	7.23	0.29	0.26	0.25	0.05
58	4.30	6.83	0.36	0.12	0.60	0.04
59	2.99	7.62	0.55	0.23	0.55	0.05
60	4.36	9.22	0.76	0.20	0.55	0.07
Mean	3.837	7.798	0.436	0.175	0.587	0.057
SD	0.761	0.963	0.150	0.050	0.239	0.013
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
76	1.21	7.18	0.27	0.16	0.27	0.03
77	1.04	6.62	0.23	0.15	0.14	0.03
78	1.36	9.99	0.32	0.11	0.32	0.07
79	0.49	3.11	0.15	0.05	0.11	0.01
80	1.01	5.13	0.22	0.12	0.14	0.02
86	0.77	6.12	0.12	0.08	0.10	0.03
87	0.84	10.33	0.24	0.08	0.20	0.06
88	1.45	8.55	0.29	0.10	0.14	0.05
89	1.05	7.18	0.17	0.07	0.22	0.03
90	1.87	6.34	0.27	0.12	0.22	0.03
Mean	1.109	7.055	0.228	0.104	0.186	0.036
SD	0.388	2.172	0.064	0.035	0.072	0.018
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
106	1.07	6.60	0.20	0.11	0.13	0.03
107	0.66	5.47	0.10	0.26	0.05	0.02
108	1.56	6.40	0.24	0.09	0.12	0.03
109	0.96	6.98	0.21	0.26	0.13	0.03
110	1.08	6.54	0.19	0.11	0.12	0.02
116	0.83	6.22	0.13	0.13	0.08	0.02
117	1.15	7.55	0.16	0.15	0.11	0.04
118	1.48	10.23	0.30	0.21	0.16	0.06
119	0.78	4.35	0.13	0.09	0.07	0.01
120	1.68	6.75	0.17	0.17	0.11	0.04
Mean	1.125	6.709	0.183	0.158	0.108	0.030
SD	0.346	1.515	0.059	0.065	0.033	0.014
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766387

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
136	0.94	5.94	0.16	0.05	0.15	0.03
137	1.98	7.88	0.21	0.22	0.19	0.03
138	0.79	4.70	0.08	0.06	0.06	0.02
139	1.49	7.57	0.17	0.10	0.20	0.03
140	3.73	7.03	0.25	0.10	0.44	0.04
146	0.92	6.73	0.22	0.11	0.19	0.03
147	1.51	7.65	0.29	0.09	0.19	0.04
148	1.41	6.83	0.27	0.09	0.26	0.02
149	0.99	6.25	0.12	0.13	0.36	0.03
150	3.58	6.05	0.27	0.12	1.01	0.06
Mean	1.734	6.663	0.204	0.107	0.305	0.033
SD	1.075	0.964	0.070	0.047	0.270	0.012
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
166	1.98	5.44	0.33	0.08	0.32	0.03
167	3.04	11.10	0.62	0.15	0.39	0.07
168	2.08	4.35	0.19	0.12	0.32	0.04
169	1.59	5.84	0.33	0.11	0.22	0.04
170	2.96	8.51	0.40	0.14	0.26	0.05
176	3.00	7.39	0.31	0.10	0.65	0.07
177	1.55	4.70	0.24	0.22	0.21	0.03
178	2.69	7.79	0.33	0.18	0.35	0.04
179	2.37	8.41	0.53	0.14	0.39	0.07
180	1.52	5.12	0.40	0.13	0.23	0.03
Mean	2.278	6.865	0.368	0.137	0.334	0.047
SD	0.619	2.142	0.128	0.040	0.130	0.017
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
196	2.16	8.66	0.20	0.10	0.20	0.06
197	2.93	6.84	0.30	0.17	0.67	0.05
198	1.77	7.22	0.11	0.13	0.17	0.03
199	1.16	7.49	0.18	0.15	0.24	0.04
200	1.78	3.77	0.24	0.16	0.21	0.01
206	2.96	6.74	0.22	0.10	0.22	0.04
207	2.54	6.38	0.19	0.12	0.41	0.04
208	5.79	10.41	0.38	0.33	0.66	0.07
209	1.84	6.50	0.15	0.25	0.26	0.04
210	2.30	6.81	0.26	0.11	0.61	0.05
Mean	2.523	7.082	0.223	0.162	0.365	0.043
SD	1.276	1.693	0.077	0.074	0.205	0.016
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
166	4.72	6.17	0.21	0.10	0.63	0.03
167	6.83	10.58	0.47	0.15	0.80	0.07
168	6.03	5.87	0.41	0.10	0.69	0.06
169	4.76	5.65	0.28	0.05	0.83	0.04
170	7.92	7.86	0.40	0.11	0.86	0.06
171	7.46	6.44	0.55	0.10	1.10	0.05
172	7.70	5.24	0.30	0.08	0.87	0.05
173	5.63	10.26	0.27	0.03	1.19	0.10
174	6.76	8.69	0.42	0.06	1.15	0.06
175	7.71	6.32	0.55	0.14	0.58	0.03
Mean	6.552	7.308	0.386	0.092	0.870	0.055
SD	1.209	1.937	0.118	0.038	0.215	0.021
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
16	0.89	3.23	0.14	0.04	0.03	0.01
17	1.27	2.93	0.16	0.10	0.03	0.01
18	0.81	4.83	0.09	0.08	0.05	0.02
19	1.29	9.38	0.25	0.21	0.12	0.03
20	0.83	9.00	0.26	0.13	0.15	0.03
21	0.66	5.76	0.16	0.07	0.08	0.01
22	0.72	4.53	0.17	0.06	0.06	0.01
23	0.88	6.72	0.22	0.09	0.13	0.02
24	1.21	6.98	0.29	0.10	0.09	0.03
25	0.89	4.48	0.15	0.06	0.03	0.02
Mean	0.945	5.784	0.189	0.094	0.077	0.019
SD	0.228	2.222	0.063	0.048	0.044	0.009
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766392

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
46	4.39	7.28	0.19	0.08	0.57	0.05
47	4.31	5.37	0.12	0.08	0.27	0.06
48	12.57	8.15	0.94	0.12	1.64	0.13
49	3.36	4.52	0.18	0.05	0.48	0.03
50	7.53	5.27	0.26	0.12	0.42	0.04
51	5.67	9.04	0.43	0.08	1.19	0.08
52	7.46	7.17	0.55	0.14	1.66	0.06
53	6.88	6.46	0.40	0.07	1.18	0.06
54	6.42	7.14	0.39	0.15	0.62	0.05
55	6.56	5.46	0.27	0.10	0.61	0.04
Mean	6.515	6.586	0.373	0.099	0.864	0.060
SD	2.556	1.428	0.239	0.032	0.511	0.028
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766393

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
76	5.45	6.73	0.73	0.21	0.61	0.03
77	3.84	6.08	0.44	0.10	0.16	0.02
78	4.10	6.02	0.38	0.16	0.57	0.05
79	2.95	4.70	0.38	0.09	0.26	0.02
80	4.81	5.41	0.47	0.10	0.35	0.04
81	3.26	3.24	0.33	0.09	0.23	0.03
82	3.83	3.75	0.30	0.38	0.21	0.04
83	5.38	7.33	0.44	0.13	1.10	0.06
84	3.59	5.61	0.50	0.14	0.97	0.05
85	4.18	8.84	0.41	0.12	0.32	0.05
Mean	4.139	5.771	0.438	0.152	0.478	0.039
SD	0.842	1.657	0.119	0.088	0.330	0.014
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766394

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
106	4.37	7.85	0.42	0.23	0.51	0.04
107	2.55	6.46	0.27	0.38	0.20	0.03
108	8.72	4.89	0.45	0.28	0.78	0.05
109	4.71	7.14	0.55	0.33	0.36	0.05
110	7.16	6.24	0.47	0.26	0.68	0.05
111	7.20	7.49	0.88	0.46	0.64	0.07
112	2.86	2.79	0.21	0.18	0.15	0.01
113	3.64	4.03	0.33	0.22	0.29	0.02
114	7.84	8.41	0.44	0.36	0.39	0.07
115	6.34	4.52	0.41	0.38	0.29	0.03
Mean	5.539	5.982	0.443	0.308	0.429	0.042
SD	2.191	1.845	0.183	0.088	0.214	0.020
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766395

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
136	7.07	5.49	0.37	0.32	0.65	0.04
137	10.93	6.49	0.68	0.72	1.33	0.08
138	4.64	6.25	0.40	0.51	0.23	0.03
139	7.28	7.57	0.52	0.54	0.34	0.05
140	6.75	5.83	0.42	0.50	0.99	0.05
141	6.78	3.49	0.33	0.51	0.38	0.02
142	5.70	5.39	0.37	0.19	0.30	0.04
143	6.93	6.85	0.18	0.58	0.53	0.05
144	8.18	5.52	0.39	0.64	0.92	0.05
145	5.32	5.77	0.38	0.57	0.60	0.02
Mean	6.958	5.865	0.404	0.508	0.627	0.043
SD	1.735	1.083	0.129	0.152	0.354	0.018
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766396

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
196	7.47	7.22	0.33	0.60	0.92	0.04
197	6.01	6.18	0.17	0.46	0.53	0.04
198	11.39	5.94	0.51	0.65	0.44	0.05
199	7.50	6.01	0.34	0.65	0.67	0.04
200	8.31	4.14	0.31	0.56	0.66	0.03
201	9.83	5.16	0.14	0.68	0.51	0.05
202	5.72	5.80	0.23	0.81	0.40	0.03
203	6.64	7.32	0.39	0.35	0.64	0.04
204	7.44	9.91	0.49	0.75	0.39	0.06
205	3.38	4.06	0.14	0.22	0.19	0.01
Mean	7.369	6.174	0.305	0.573	0.535	0.039
SD	2.215	1.707	0.135	0.182	0.200	0.014
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766397

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
176	0.63	4.73	0.12	0.08	0.05	0.02
177	0.96	3.88	0.13	0.15	0.03	0.01
178	0.48	3.88	0.13	0.06	0.06	0.01
179	1.33	6.18	0.32	0.12	0.07	0.02
180	0.61	3.25	0.10	0.11	0.04	0.01
Mean	0.802	4.384	0.160	0.104	0.050	0.014
SD	0.344	1.134	0.090	0.035	0.016	0.005
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766398

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
26	0.95	6.87	0.22	0.06	0.08	0.02
27	1.21	4.04	0.12	0.22	0.03	0.01
28	1.10	5.12	0.25	0.10	0.10	0.02
29	1.00	3.73	0.19	0.32	0.04	0.01
30	0.43	3.80	0.15	0.15	0.05	0.01
Mean	0.938	4.712	0.186	0.170	0.060	0.014
SD	0.301	1.330	0.052	0.103	0.029	0.005
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766399

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
56	1.19	5.93	0.21	0.12	0.08	0.03
57	1.06	5.99	0.13	0.17	0.10	0.02
58	1.00	6.35	0.22	0.09	0.13	0.01
59	0.69	2.56	0.07	0.05	0.03	0.01
60	1.94	9.24	0.37	0.17	0.10	0.04
Mean	1.176	6.014	0.200	0.120	0.088	0.022
SD	0.465	2.369	0.113	0.052	0.037	0.013
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766400

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
86	0.87	5.84	0.17	0.06	0.08	0.01
87	1.12	8.33	0.34	0.10	0.12	0.03
88	1.35	6.00	0.32	0.18	0.09	0.02
89	0.86	4.46	0.13	0.06	0.04	0.01
90	0.84	3.20	0.15	0.23	0.03	0.00
Mean	1.008	5.566	0.222	0.126	0.072	0.014
SD	0.223	1.919	0.100	0.076	0.037	0.011
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766401

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
116	1.23	2.97	0.11	0.23	0.03	0.01
117	1.49	6.42	0.28	0.11	0.13	0.01
118	1.56	9.16	0.31	0.24	0.14	0.04
119	0.78	3.10	0.15	0.08	0.05	0.00
120	1.28	6.03	0.25	0.13	0.05	0.02
Mean	1.268	5.536	0.220	0.158	0.080	0.016
SD	0.306	2.583	0.086	0.073	0.051	0.015
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766402

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
146	1.11	5.98	0.27	0.13	0.06	0.02
147	1.05	3.59	0.18	0.06	0.04	0.00
148	1.32	3.90	0.15	0.09	0.05	0.01
149	1.08	8.46	0.23	0.16	0.10	0.02
150	1.24	4.44	0.23	0.09	0.07	0.01
Mean	1.160	5.274	0.212	0.106	0.064	0.012
SD	0.115	2.004	0.047	0.039	0.023	0.008
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766403

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	Neut (x10E3/µL)	Lym (x10E3/µL)	Mono (x10E3/µL)	Eos (x10E3/µL)	LUC (x10E3/µL)	Baso (x10E3/µL)
206	1.21	4.67	0.15	0.20	0.07	0.01
207	1.45	6.95	0.21	0.14	0.09	0.02
208	1.18	8.01	0.25	0.15	0.08	0.02
209	0.67	2.69	0.10	0.06	0.03	0.01
210	1.61	5.19	0.13	0.15	0.05	0.03
Mean	1.224	5.502	0.168	0.140	0.064	0.018
SD	0.357	2.067	0.061	0.050	0.024	0.008
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0766404

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
16	53.1	1.15	21.59
17	55.4	1.17	21.20
18	57.2	1.19	20.87
19	55.4	1.16	21.04
20	55.5	1.19	21.40
26	55.8	1.19	21.25
27	56.4	1.17	20.81
28	52.4	1.12	21.31
29	55.1	1.17	21.20
30	51.0	1.08	21.22
Mean	54.73	1.159	21.189
SD	1.93	0.035	0.234
N	10	10	10

FDA-CBER-2021-5683-0766405

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
46	56.3	1.19	21.16
47	54.9	1.17	21.31
48	56.9	1.19	21.01
49	54.0	1.14	21.07
50	54.7	1.18	21.63
56	56.5	1.18	20.96
57	54.1	1.17	21.59
58	55.7	1.18	21.21
59	56.2	1.19	21.24
60	55.0	1.17	21.22
Mean	55.43	1.176	21.240
SD	1.03	0.015	0.223
N	10	10	10

FDA-CBER-2021-5683-0766406

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
76	52.9	1.14	21.55
77	53.5	1.14	21.35
78	56.2	1.22	21.65
79	53.8	1.18	21.94
80	53.5	1.15	21.42
86	51.9	1.14	21.91
87	56.1	1.18	21.07
88	53.8	1.16	21.55
89	55.0	1.19	21.69
90	54.6	1.20	21.93
Mean	54.13	1.170	21.606
SD	1.36	0.028	0.281
N	10	10	10

FDA-CBER-2021-5683-0766407

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
106	57.9	1.21	20.89
107	54.2	1.13	20.92
108	54.2	1.15	21.20
109	58.0	1.23	21.29
110	56.5	1.18	20.91
116	56.2	1.18	21.05
117	53.5	1.10	20.60
118	53.9	1.14	21.16
119	54.2	1.17	21.57
120	53.5	1.13	21.10
Mean	55.21	1.162	21.069
SD	1.77	0.040	0.264
N	10	10	10

FDA-CBER-2021-5683-0766408

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
136	51.6	1.07	20.75
137	54.1	1.15	21.20
138	52.2	1.14	21.84
139	52.8	1.12	21.26
140	54.0	1.16	21.45
146	53.1	1.12	21.11
147	54.6	1.16	21.27
148	56.9	1.22	21.38
149	52.4	1.13	21.50
150	51.8	1.11	21.43
Mean	53.35	1.138	21.319
SD	1.61	0.039	0.284
N	10	10	10

FDA-CBER-2021-5683-0766409

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
166	53.5	1.18	21.97
167	56.0	1.22	21.81
168	51.3	1.11	21.59
169	52.5	1.13	21.55
170	52.0	1.16	22.33
176	53.9	1.16	21.60
177	51.6	1.11	21.50
178	54.1	1.16	21.37
179	56.1	1.22	21.69
180	51.5	1.13	21.97
Mean	53.25	1.158	21.738
SD	1.78	0.040	0.286
N	10	10	10

FDA-CBER-2021-5683-0766410

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters		
	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
196	53.4	1.16	21.80
197	54.2	1.17	21.66
198	51.7	1.12	21.56
199	55.4	1.18	21.29
200	51.8	1.13	21.92
206	52.8	1.31	24.71
207	53.0	1.13	21.24
208	49.4	1.06	21.46
209	52.5	1.13	21.54
210	56.0	1.18	21.15
Mean	53.02	1.157	21.833
SD	1.91	0.065	1.040
N	10	10	10

FDA-CBER-2021-5683-0766411

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
166	8.9	18.9	272.0	53.9	1.18	21.95
167	9.4	17.7	314.0	55.1	1.19	21.55
168	9.1	17.9	295.0	50.5	1.09	21.56
169	9.4	19.3	247.0	52.6	1.13	21.39
170	9.4	19.3	256.0	51.9	1.13	21.74
171	10.1	19.1	243.0	52.3	1.14	21.73
172	9.4	19.1	283.0	53.7	1.17	21.86
173	9.6	19.4	261.0	48.8	1.07	21.89
174	9.9	18.6	246.0	51.6	1.13	21.85
175	9.2	17.5	256.0	54.4	1.17	21.48
Mean	9.44	18.68	267.30	52.48	1.140	21.700
SD	0.36	0.72	23.49	1.91	0.039	0.193
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766412

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
16	9.1	17.7	99.8	54.0	1.13	20.97
17	9.7	14.9	83.3	55.8	1.17	20.99
18	9.1	14.9	88.2	56.8	1.16	20.46
19	8.6	16.8	266.0	54.4	1.15	21.05
20	9.0	14.3	95.0	54.7	1.16	21.12
21	9.4	14.1	86.9	56.1	1.16	20.68
22	8.8	14.9	82.8	51.8	1.09	21.13
23	9.0	15.1	85.9	55.5	1.14	20.54
24	9.3	13.7	93.5	56.2	1.18	20.91
25	8.3	14.4	163.0	55.1	1.15	20.95
Mean	9.03	15.08	114.44	55.04	1.149	20.880
SD	0.40	1.24	58.30	1.43	0.025	0.237
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766413

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
46	9.2	17.0	297.0	55.2	1.16	20.99
47	9.6	18.8	327.0	55.7	1.15	20.65
48	9.3	17.6	316.0	57.1	1.17	20.43
49	9.2	16.4	273.0	55.6	1.16	20.81
50	9.8	18.7	325.0	55.7	1.15	20.61
51	9.4	17.1	349.0	53.9	1.12	20.83
52	9.1	19.3	308.0	55.5	1.14	20.61
53	8.6	16.7	308.0	55.3	1.15	20.83
54	8.9	18.2	288.0	53.8	1.12	20.78
55	8.2	16.1	349.0	55.2	1.17	21.23
Mean	9.13	17.59	314.00	55.30	1.149	20.777
SD	0.47	1.11	24.64	0.94	0.018	0.224
N	10	10	10	10	10	10

FDA-CBER-2021-5683-0766414

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
76	9.6	18.7	258.0	52.9	1.09	20.69
77	9.0	18.7	246.0	53.9	1.12	20.72
78	8.7	17.5	271.0	55.3	1.19	21.50
79	NV !	NV !	NV !	54.9	1.17	21.23
80	9.4	18.5	256.0	51.9	1.11	21.31
81	9.1	17.7	228.0	53.4	1.14	21.44
82	5.3	16.8	441.0	51.2	1.11	21.73
83	9.5	19.6	281.0	50.1	1.09	21.70
84	8.7	21.7	296.0	52.2	1.12	21.52
85	9.0	18.1	241.0	50.0	1.07	21.44
Mean	8.70	18.59	279.78	52.58	1.121	21.328
SD	1.32	1.42	63.93	1.84	0.037	0.362
N	9	9	9	10	10	10

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
106	NV !	NV !	NV !	57.4	1.17	20.38
107	9.4	14.9	250.0	53.2	1.10	20.67
108	9.5	15.4	315.0	53.9	1.10	20.48
109	8.8	14.2	235.0	58.1	1.19	20.53
110	9.1	16.0	306.0	55.8	1.16	20.78
111	9.1	14.8	279.0	52.7	1.10	20.79
112	9.6	14.2	283.0	51.9	1.05	20.31
113	8.9	14.7	275.0	54.2	1.09	20.15
114	9.9	14.9	287.0	53.3	1.10	20.59
115	9.8	13.6	306.0	54.8	1.14	20.86
Mean	9.34	14.74	281.78	54.53	1.120	20.554
SD	0.39	0.70	26.36	2.02	0.043	0.230
N	9	9	9	10	10	10

! = Result Comment

FDA-CBER-2021-5683-0766416

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
136	9.0	16.9	312.0	50.0	1.06	21.15
137	8.6	14.4	365.0	52.2	1.10	20.97
138	9.0	17.1	247.0	52.2	1.09	20.95
139	8.5	18.1	311.0	52.2	1.09	20.86
140	9.3	17.9	275.0	53.3	1.12	21.08
141	9.5	17.4	304.0	49.6	1.06	21.47
142	9.2	15.8	284.0	53.9	1.14	21.15
143	10.3	19.6	311.0	52.2	1.13	21.54
144	9.3	16.8	312.0	53.0	1.13	21.39
145	9.7	17.5	270.0	50.0	1.08	21.65
Mean	9.24	17.15	299.10	51.86	1.100	21.221
SD	0.53	1.38	32.24	1.49	0.029	0.273
N	10	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
196	9.4	17.8	290.0	53.0	1.11	20.95
197	NV !	NV !	NV !	54.1	1.13	20.91
198	9.7	18.0	314.0	52.3	1.08	20.61
199	9.6	16.8	306.0	53.8	1.14	21.12
200	9.3	18.2	293.0	50.6	1.10	21.66
201	9.9	17.0	321.0	54.5	1.16	21.36
202	NV !	NV !	NV !	53.7	1.12	20.78
203	8.5	20.0	272.0	52.2	1.11	21.27
204	9.6	17.1	290.0	53.0	1.11	20.87
205	9.1	17.6	296.0	51.2	1.10	21.45
Mean	9.39	17.81	297.75	52.84	1.116	21.098
SD	0.44	1.01	15.50	1.27	0.023	0.331
N	8	8	8	10	10	10

! = Result Comment

FDA-CBER-2021-5683-0766418

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
176	9.4	14.2	89.0	52.9	1.10	20.73
177	9.3	15.7	92.0	50.4	1.06	21.04
178	8.7	17.0	156.0	51.8	1.08	20.83
179	8.8	15.1	87.5	53.0	1.14	21.61
180	10.2	14.6	95.5	50.8	1.05	20.75
Mean	9.28	15.32	104.00	51.78	1.086	20.992
SD	0.60	1.09	29.23	1.18	0.036	0.367
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
26	8.9	17.1	91.8	52.9	1.09	20.59
27	9.4	17.9	90.5	54.6	1.12	20.55
28	10.4	NV !	NV !	50.7	1.06	20.83
29	8.9	16.4	93.8	52.3	1.08	20.69
30	9.1	16.8	76.9	49.5	1.04	20.93
Mean	9.34	17.05	88.25	52.00	1.078	20.718
SD	0.63	0.64	7.69	1.97	0.030	0.160
N	5	4	4	5	5	5

! = Result Comment

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
56	9.4	15.1	89.8	54.3	1.10	20.21
57	8.9	NV !	NV !	52.7	1.09	20.65
58	9.3	14.7	89.5	53.7	1.09	20.25
59	9.6	16.3	86.8	55.9	1.13	20.24
60	9.6	16.2	81.0	51.3	1.06	20.66
Mean	9.36	15.58	86.78	53.58	1.094	20.402
SD	0.29	0.80	4.08	1.72	0.025	0.231
N	5	4	4	5	5	5

! = Result Comment

FDA-CBER-2021-5683-0766421

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
86	9.4	17.1	87.0	50.3	1.05	20.91
87	9.6	16.6	75.3	52.8	1.09	20.69
88	9.1	16.1	83.6	53.4	1.09	20.45
89	9.3	18.1	NM !	53.7	1.11	20.57
90	8.9	19.7	222.0	52.3	1.09	20.91
Mean	9.26	17.52	116.98	52.50	1.086	20.706
SD	0.27	1.43	70.19	1.34	0.022	0.205
N	5	5	4	5	5	5

! = Result Comment

FDA-CBER-2021-5683-0766422

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
116	8.9	18.7	86.6	52.7	1.09	20.77
117	9.1	15.7	78.9	49.9	1.02	20.55
118	9.2	18.3	142.0	50.1	1.02	20.41
119	9.3	15.4	82.1	53.0	1.11	20.98
120	9.3	16.2	94.6	50.1	1.02	20.46
Mean	9.16	16.86	96.84	51.16	1.052	20.634
SD	0.17	1.53	25.92	1.55	0.044	0.238
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
146	8.7	16.8	89.9	50.9	1.03	20.35
147	8.8	20.4	83.3	54.2	1.10	20.23
148	8.6	17.3	87.3	53.9	1.11	20.60
149	9.2	18.5	99.0	50.0	1.04	20.88
150	9.0	16.9	74.5	51.8	1.06	20.52
Mean	8.86	17.98	86.80	52.16	1.068	20.516
SD	0.24	1.51	8.98	1.84	0.036	0.249
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters					
	PT (Seconds)	aPTT (Seconds)	Fibrinogen (mg/dL)	MCV (fL)	MCH (fmol)	MCHC (mmol/L)
206	8.8	15.6	79.8	51.2	1.04	20.31
207	8.9	16.9	76.2	52.0	1.08	20.81
208	8.6	15.7	102.0	48.5	0.99	20.41
209	9.5	17.0	75.1	52.7	1.09	20.69
210	9.0	16.3	90.3	54.0	1.12	20.82
Mean	8.96	16.30	84.68	51.68	1.064	20.608
SD	0.34	0.65	11.39	2.05	0.050	0.235
N	5	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
16	8.4	0.73	90.7	10.6	21.7
17	8.4	0.82	77.0	11.1	18.9
18	8.1	0.71	73.7	12.1	21.0
19	7.2	0.70	69.0	11.6	20.4
20	8.1	0.66	86.2	11.0	21.2
26	8.4	0.74	71.1	10.2	19.0
27	6.8	0.73	68.9	10.9	21.7
28	7.3	0.62	78.2	11.0	22.8
29	7.5	0.94	75.3	11.1	19.9
30	7.6	0.92	90.1	11.9	21.6
Mean	7.78	0.757	78.02	11.15	20.82
SD	0.58	0.105	8.25	0.58	1.26
N	10	10	10	10	10

FDA-CBER-2021-5683-0766426

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
46	9.0	0.56	84.2	11.1	22.1
47	7.9	0.66	93.1	11.2	22.2
48	8.2	0.84	90.7	11.6	21.1
49	8.6	0.49	77.1	10.8	22.3
50	8.8	0.53	100.8	10.4	23.6
56	7.9	0.59	89.0	12.2	21.7
57	7.4	0.61	85.9	10.8	21.9
58	8.1	0.59	90.9	11.1	22.2
59	8.5	0.67	77.1	11.8	20.0
60	8.2	0.65	84.9	11.4	21.9
Mean	8.26	0.619	87.37	11.24	21.90
SD	0.48	0.097	7.22	0.53	0.92
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
76	6.7	0.96	85.1	10.7	24.2
77	6.3	0.67	69.7	10.4	23.8
78	7.1	0.91	85.4	11.8	22.0
79	6.9	0.50	94.0	10.3	25.6
80	7.0	0.75	98.0	10.7	24.4
86	7.3	0.63	93.0	10.5	22.6
87	6.5	0.93	72.9	11.3	22.9
88	6.9	0.66	79.3	10.5	22.8
89	7.4	0.68	94.1	11.1	24.0
90	7.1	0.67	73.4	11.4	22.0
Mean	6.92	0.736	84.49	10.87	23.43
SD	0.34	0.150	10.23	0.50	1.16
N	10	10	10	10	10

FDA-CBER-2021-5683-0766428

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
106	7.6	0.82	77.2	13.2	22.0
107	7.6	0.70	86.9	11.8	21.8
108	7.0	0.66	80.2	11.5	23.2
109	7.6	0.96	80.5	12.1	20.5
110	8.1	0.85	73.5	11.4	20.1
116	7.2	0.72	67.5	11.4	21.3
117	8.1	0.66	87.8	12.0	21.2
118	9.2	0.80	86.1	12.5	21.0
119	7.7	0.69	85.7	11.0	22.1
120	8.4	0.84	84.1	11.6	21.4
Mean	7.85	0.770	80.95	11.85	21.46
SD	0.63	0.099	6.60	0.64	0.88
N	10	10	10	10	10

FDA-CBER-2021-5683-0766429

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
136	7.0	0.61	83.4	12.7	23.7
137	7.1	0.78	64.7	10.3	22.7
138	7.0	0.68	87.0	11.9	24.5
139	7.1	0.82	81.0	11.7	22.9
140	7.0	0.68	91.8	10.8	24.8
146	7.7	0.66	85.7	11.3	23.4
147	6.4	0.77	80.9	10.7	23.7
148	7.5	0.79	80.2	11.9	23.4
149	7.5	0.90	91.3	12.6	23.8
150	7.2	0.79	97.7	12.2	25.1
Mean	7.15	0.748	84.37	11.61	23.80
SD	0.36	0.088	8.93	0.82	0.78
N	10	10	10	10	10

FDA-CBER-2021-5683-0766430

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
166	7.4	0.67	79.5	11.3	23.0
167	7.4	0.60	83.9	11.4	22.7
168	6.7	0.78	91.6	11.9	24.7
169	7.0	0.86	83.8	11.3	22.4
170	6.6	0.60	84.0	10.8	22.9
176	7.6	0.74	90.8	10.9	23.4
177	7.2	0.75	70.1	10.7	21.5
178	7.7	0.62	94.9	11.5	23.8
179	6.7	0.77	86.0	12.3	24.1
180	7.6	0.77	100.3	11.6	24.3
Mean	7.19	0.716	86.49	11.37	23.28
SD	0.41	0.089	8.46	0.50	0.97
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
196	6.9	0.66	82.2	10.2	23.7
197	7.3	0.72	90.5	12.0	24.5
198	7.5	0.69	89.5	10.8	25.6
199	7.2	0.73	65.7	11.7	21.9
200	6.6	0.64	76.3	10.2	24.2
206	7.7	0.67	94.9	11.1	24.0
207	6.5	0.66	71.0	10.5	25.0
208	8.0	0.77	83.9	12.0	22.9
209	7.4	0.93	93.5	11.7	23.6
210	7.4	0.86	78.4	12.4	23.7
Mean	7.25	0.733	82.59	11.26	23.91
SD	0.47	0.095	9.77	0.81	1.04
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
166	8.4	0.47	97.8	13.3	24.1
167	9.1	0.49	105.4	12.4	23.1
168	8.5	0.56	99.7	12.2	23.7
169	8.6	0.66	98.3	12.6	22.5
170	8.0	0.46	101.8	11.9	23.7
171	7.8	0.39	92.1	10.7	22.5
172	11.3	0.33	93.7	12.8	23.3
173	8.6	0.40	99.6	11.6	25.2
174	7.9	0.44	107.4	11.3	23.7
175	8.2	0.64	99.4	12.9	23.9
Mean	8.64	0.484	99.52	12.17	23.57
SD	1.01	0.107	4.66	0.80	0.79
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
16	11.1	1.08	56.3	15.1	18.8
17	12.0	1.52	57.8	15.3	15.8
18	10.6	0.98	54.2	14.1	18.6
19	10.3	1.14	57.5	14.3	17.4
20	10.6	0.94	57.4	13.4	18.0
21	10.7	0.99	58.9	13.7	17.3
22	10.4	1.22	56.4	14.6	18.9
23	10.9	1.13	54.2	14.2	16.8
24	10.6	1.24	59.1	13.8	18.7
25	10.6	1.32	54.5	14.0	17.4
Mean	10.78	1.156	56.63	14.25	17.77
SD	0.48	0.177	1.84	0.60	1.01
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
46	11.8	0.54	74.0	16.0	20.2
47	11.8	0.61	65.4	16.1	18.7
48	11.0	1.01	63.8	15.7	18.8
49	13.5	0.54	70.1	17.2	20.6
50	12.9	0.68	70.4	16.5	20.6
51	11.1	0.75	63.6	15.1	19.2
52	14.3	0.89	81.6	16.0	21.1
53	10.9	0.86	67.6	15.0	19.6
54	11.0	0.73	67.1	14.8	19.4
55	11.0	0.72	61.8	15.9	19.0
Mean	11.93	0.733	68.54	15.83	19.72
SD	1.22	0.153	5.88	0.73	0.85
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
76	9.1	0.84	81.6	13.1	20.0
77	8.3	0.71	74.1	13.7	19.1
78	8.4	0.75	75.4	13.3	18.9
79	9.4	0.46	83.8	14.4	20.3
80	9.1	0.58	93.5	12.5	21.4
81	8.6	0.50	83.2	12.9	20.5
82	8.2	0.69	94.0	12.7	20.9
83	11.4	0.67	80.8	12.8	20.6
84	8.1	0.42	76.2	12.1	21.5
85	8.7	0.57	84.6	12.6	20.2
Mean	8.93	0.619	82.72	13.01	20.34
SD	0.97	0.135	6.86	0.66	0.86
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
106	10.7	1.09	61.3	15.2	19.0
107	10.2	0.82	62.9	14.5	19.3
108	10.3	0.95	69.2	15.9	20.4
109	10.4	0.97	53.7	15.2	17.8
110	10.2	1.00	61.0	14.7	19.9
111	10.3	0.91	58.3	14.6	19.5
112	9.8	0.81	67.1	15.0	20.8
113	10.6	0.64	57.0	14.4	18.9
114	11.7	1.02	63.5	16.3	19.9
115	11.3	1.03	58.7	15.4	17.8
Mean	10.55	0.924	61.27	15.12	19.33
SD	0.56	0.134	4.66	0.62	1.00
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
136	8.7	0.70	86.6	14.5	21.9
137	9.0	0.65	74.2	12.7	21.4
138	8.8	0.66	70.5	13.9	20.1
139	9.7	0.54	89.9	14.1	20.2
140	9.3	0.55	81.9	13.5	21.1
141	9.0	0.74	82.8	11.9	20.8
142	8.8	0.53	80.9	12.8	21.2
143	11.2	0.62	94.9	12.8	23.3
144	10.0	0.85	90.3	13.9	21.3
145	8.9	0.70	90.6	12.9	22.3
Mean	9.34	0.654	84.26	13.30	21.36
SD	0.78	0.100	7.72	0.80	0.96
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
196	8.9	0.71	76.4	14.5	21.1
197	9.1	0.69	75.6	14.9	20.7
198	9.5	0.77	81.2	13.2	21.8
199	8.8	0.58	74.1	13.5	20.4
200	10.0	0.66	93.1	13.5	22.6
201	9.5	0.71	91.2	12.9	21.6
202	9.5	0.56	79.8	12.7	19.4
203	8.6	0.65	79.3	12.6	20.4
204	8.8	0.79	72.2	12.7	20.3
205	12.6	0.45	83.6	13.2	21.9
Mean	9.53	0.657	80.65	13.37	21.02
SD	1.16	0.103	6.96	0.78	0.96
N	10	10	10	10	10

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
176	7.9	0.96	67.5	12.9	20.7
177	7.7	0.77	64.4	12.9	19.9
178	9.0	0.75	79.2	13.2	20.4
179	7.9	0.78	87.9	12.5	22.3
180	7.4	0.82	62.0	13.3	20.5
Mean	7.98	0.816	72.20	12.96	20.76
SD	0.61	0.084	10.98	0.31	0.91
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
26	8.8	0.88	62.8	10.9	18.2
27	8.0	0.81	61.6	11.7	18.5
28	9.2	0.47	68.5	12.1	17.6
29	8.2	1.02	63.9	11.3	18.0
30	8.3	0.83	74.7	12.2	19.3
Mean	8.50	0.802	66.30	11.64	18.32
SD	0.49	0.203	5.37	0.55	0.64
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
56	8.2	0.93	66.7	13.1	18.6
57	8.1	0.75	63.5	12.8	18.2
58	7.9	0.80	60.7	13.6	20.2
59	9.1	0.75	68.4	14.2	18.0
60	8.9	0.71	75.0	13.2	19.5
Mean	8.44	0.788	66.86	13.38	18.90
SD	0.53	0.086	5.43	0.54	0.93
N	5	5	5	5	5

FDA-CBER-2021-5683-0766442

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
86	7.3	0.73	72.1	12.7	20.7
87	7.4	0.98	64.3	12.6	19.8
88	8.2	0.72	72.3	14.5	20.7
89	9.1	0.87	75.4	13.4	19.5
90	8.4	0.69	77.2	12.5	19.6
Mean	8.08	0.798	72.26	13.14	20.06
SD	0.75	0.123	4.94	0.84	0.59
N	5	5	5	5	5

FDA-CBER-2021-5683-0766443

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
116	8.0	0.66	74.4	12.7	20.0
117	9.2	0.77	77.4	13.4	18.9
118	9.3	0.86	72.3	12.7	19.4
119	7.8	0.59	68.0	13.2	20.1
120	9.0	0.69	73.7	13.4	19.0
Mean	8.66	0.714	73.16	13.08	19.48
SD	0.71	0.104	3.43	0.36	0.55
N	5	5	5	5	5

FDA-CBER-2021-5683-0766444

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
146	8.3	0.60	69.9	13.4	19.7
147	7.8	0.85	63.0	13.2	19.0
148	7.5	0.60	60.3	13.1	20.3
149	7.3	0.67	89.8	13.4	23.2
150	7.8	0.74	76.4	13.7	21.0
Mean	7.74	0.692	71.88	13.36	20.64
SD	0.38	0.106	11.82	0.23	1.61
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Haematological Parameters				
	MPV (fL)	PCT (%)	PDW (%)	RDW (%)	MPC (g/dL)
206	6.9	0.55	67.1	13.0	21.8
207	7.9	0.75	70.6	13.1	21.0
208	8.2	0.85	75.3	13.6	21.6
209	7.6	0.81	71.4	13.4	20.8
210	8.2	0.94	77.3	13.7	19.6
Mean	7.76	0.780	72.34	13.36	20.96
SD	0.54	0.146	4.02	0.30	0.86
N	5	5	5	5	5

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	HGB	Quality Flag	I (Include)
	10	6	Male	152	RBC	Quality Flag	I (Include)
	10	6	Male	152	WBC	Quality Flag	I (Include)
	10	6	Male	152	Reticulocyte (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Reticulocyte (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	PLT	Quality Flag	I (Include)
	10	6	Male	152	HCT	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	Neutrophils (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Lymphocytes (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Monocytes (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Eosinophils (Relative)	Quality Flag	I (Include)
	10	6	Male	152	Large Uncla Cells Rel	Quality Flag	I (Include)
	10	6	Male	152	Basophils (Relative)	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	Neutrophils (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Lymphocytes (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Monocytes (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Eosinophils (Absolute)	Quality Flag	I (Include)
	10	6	Male	152	Large Unclas sified Cells	Quality Flag	I (Include)
	10	6	Male	152	Basophils (Absolute)	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	MCV	Quality Flag	I (Include)
	10	6	Male	152	MCH	Quality Flag	I (Include)
	10	6	Male	152	MCHC	Quality Flag	I (Include)
	17	1	Male	2	PT	Replacement	NV
			Comment:	Sample clotted			
	17	1	Male	2	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	1	Male	2	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	3	Male	62	PT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Male	62	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Male	62	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10	6	Male	152	MPV	Quality Flag	I (Include)
	10	6	Male	152	Plateletcrit	Quality Flag	I (Include)
	10	6	Male	152	Platlet Dist Width	Quality Flag	I (Include)
	10	6	Male	152	RDW	Quality Flag	I (Include)
	10	6	Male	152	MPC	Quality Flag	I (Include)

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
				Comments and Markers			
	17	3	Female	79	PT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Female	79	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	3	Female	79	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	4	Female	106	PT	Replacement	NV
			Comment:	Sample clotted			
	17	4	Female	106	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	4	Female	106	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	197	PT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	197	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	197	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	202	PT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	202	aPTT	Replacement	NV
			Comment:	Sample clotted			
	17	7	Female	202	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	38	1	Female	28	aPTT	Replacement	NV
			Comment:	Sample clotted			
	38	1	Female	28	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			

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TABLE 6-2 Haematological Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	38	2	Female	57	aPTT	Replacement	NV
			Comment:	Sample clotted			
	38	2	Female	57	Fibrinogen	Replacement	NV
			Comment:	Sample clotted			
	38	3	Female	89	Fibrinogen	Replacement	NM
			Comment:	No Measurement			

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a1]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a2]	Glucose (mmol/L) [a2]
Group 1: Control	Mean	29.48	27.12	1.087	3.71	1.982	39.6	9.142
	SD	0.68	0.71	0.029	0.70	0.371	2.1	0.548
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	26.70**	29.70**	0.901**	3.24	1.611*	37.6	8.973
	SD	0.41	1.56	0.045	0.46	0.348	2.1	0.493
	N	10	10	10	10	10	10	10
	%Diff	-9.4	9.5	-17.1	-12.7	-18.7	-5.1	-1.8
Group 3: 10 µg/ animal BNT162a1	Mean	27.48**	27.62	0.996**	2.72**	1.730	43.2**	6.324**
	SD	0.70	0.99	0.036	0.39	0.265	2.5	0.663
	N	10	10	10	10	10	10	10
	%Diff	-6.8	1.8	-8.4	-26.7	-12.7	9.1	-30.8
Group 4: 30 µg/ animal BNT162b1	Mean	28.27**	31.43**	0.902**	3.26	1.647	39.7	8.610
	SD	0.62	1.98	0.042	0.44	0.233	1.6	0.443
	N	10	10	10	10	10	10	10
	%Diff	-4.1	15.9	-17.1	-12.1	-16.9	0.3	-5.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	27.41**	29.59**	0.929**	2.70**	1.458**	43.5**	6.074**
100 µg/	SD	0.63	1.87	0.051	0.24	0.358	3.1	0.703
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-7.0	9.1	-14.6	-27.2	-26.4	9.8	-33.6
Group 6:	Mean	27.22**	28.88*	0.944**	2.64**	1.598*	42.5**	6.837**
30 µg/	SD	0.44	1.04	0.038	0.23	0.225	4.5	1.050
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-7.7	6.5	-13.2	-28.8	-19.4	7.3	-25.2
Group 7:	Mean	26.79**	29.11*	0.923**	2.78**	1.478**	43.6*	6.753**
100 µg/	SD	0.86	1.83	0.051	0.32	0.221	4.6	1.946
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-9.1	7.3	-15.1	-25.1	-25.4	10.1	-26.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766455

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	27.32 n	28.08 n	0.975 n	3.12 n	1.227 n	44.6 n	8.840 n
	SD	0.87	1.60	0.042	0.39	0.191	4.0	1.072
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766456

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Cholesterol (total) (mmol/L) [a2]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 1: Control	Mean	28.34	25.36	1.119	2.38	1.894	46.0	9.517
	SD	1.08	1.40	0.048	0.26	0.369	2.4	1.289
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	26.78**	27.82**	0.963**	3.34**	1.184**	47.0	8.263
	SD	0.61	1.08	0.026	0.28	0.293	4.0	1.061
	N	10	10	10	10	10	10	10
	%Diff	-5.5	9.7	-13.9	40.3	-37.5	2.2	-13.2
Group 3: 10 µg/ animal BNT162a1	Mean	26.67**	27.03	0.988**	3.13**	1.485*	48.4	8.385
	SD	0.84	1.39	0.037	0.40	0.202	2.0	0.884
	N	10	10	10	10	10	10	10
	%Diff	-5.9	6.6	-11.7	31.5	-21.6	5.2	-11.9
Group 4: 30 µg/ animal BNT162b1	Mean	27.23**	30.07**	0.908**	2.86	1.135**	47.1	8.697
	SD	0.66	1.72	0.048	0.28	0.164	2.1	0.945
	N	10	10	10	10	10	10	10
	%Diff	-3.9	18.6	-18.9	20.2	-40.1	2.4	-8.6

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766457

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	27.26**	32.04**	0.853**	3.48**	1.298**	50.6**	8.165
100 µg/	SD	0.70	1.77	0.044	0.75	0.246	3.2	1.205
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-3.8	26.3	-23.8	46.2	-31.5	10.0	-14.2
Group 7:	Mean	26.68**	31.22**	0.856**	3.40**	1.290**	51.5**	8.930
100 µg/	SD	0.47	1.29	0.029	0.36	0.147	3.7	0.918
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-5.9	23.1	-23.6	42.9	-31.9	12.0	-6.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$

FDA-CBER-2021-5683-0766458

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	27.92 n	27.88 n	1.002 n	3.04 n	1.518 n	49.8 n	9.060 n
	SD	0.72	0.87	0.034	0.11	0.066	2.3	1.876
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766459

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 1: Control	Mean	28.88	27.32	1.057	2.96	1.478	48.0	9.988
	SD	0.92	0.53	0.038	0.55	0.184	2.7	2.833
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	28.44	26.96	1.057	3.10	1.706	48.8	10.420
	SD	0.84	1.27	0.054	0.59	0.429	2.2	1.641
	N	5	5	5	5	5	5	5
	%Diff	-1.5	-1.3	-0.1	4.7	15.4	1.7	4.3
Group 3: 10 µg/ animal BNT162a1	Mean	28.40	25.00	1.137	2.94	1.664	48.8	10.504
	SD	0.92	0.92	0.063	0.36	0.249	1.9	0.898
	N	5	5	5	5	5	5	5
	%Diff	-1.7	-8.5	7.6	-0.7	12.6	1.7	5.2
Group 4: 30 µg/ animal BNT162b1	Mean	28.34	28.66	0.994	2.54	1.818	53.2**	9.794
	SD	0.76	2.42	0.083	0.38	0.269	1.3	1.207
	N	5	5	5	5	5	5	5
	%Diff	-1.9	4.9	-6.0	-14.2	23.0	10.8	-1.9

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	28.46	24.94	1.150	2.76	1.646	50.0	10.282
100 µg/	SD	0.78	2.59	0.112	0.30	0.183	3.5	1.654
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.5	-8.7	8.8	-6.8	11.4	4.2	2.9
Group 7:	Mean	29.14	27.66	1.057	2.88	1.908	48.6	9.008
100 µg/	SD	0.51	1.67	0.070	0.13	0.288	1.7	0.858
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	0.9	1.2	-0.1	-2.7	29.1	1.3	-9.8

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a1]	Tri-glycerides (mmol/L) [a2]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a1]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a1]
Group 1: Control	Mean	2.563	56.6	1.911	5.954	2.824	100.9	4.393
	SD	0.165	1.2	0.680	0.858	0.058	0.7	0.307
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	2.555	56.4	1.127**	6.670	2.798	101.0	4.478
	SD	0.081	1.8	0.400	0.444	0.084	0.9	0.274
	N	10	10	10	10	10	10	10
	%Diff	-0.3	-0.4	-41.0	12.0	-0.9	0.1	1.9
Group 3: 10 µg/ animal BNT162a1	Mean	2.695	55.1	0.573**	7.432	2.635**	102.1**	3.984**
	SD	0.136	1.4	0.170	1.467	0.076	0.7	0.190
	N	10	10	10	10	10	10	10
	%Diff	5.2	-2.7	-70.0	24.8	-6.7	1.2	-9.3
Group 4: 30 µg/ animal BNT162b1	Mean	2.338*	59.7**	1.504	6.626	2.842	101.0	4.411
	SD	0.144	2.5	0.360	0.739	0.061	0.7	0.224
	N	10	10	10	10	10	10	10
	%Diff	-8.8	5.5	-21.3	11.3	0.6	0.1	0.4

[a] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett: ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.609	57.0	0.507**	7.586	2.639**	103.0**	3.925**
100 µg/	SD	0.087	2.3	0.236	1.408	0.107	0.5	0.217
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	1.8	0.7	-73.5	27.4	-6.6	2.1	-10.7
Group 6:	Mean	2.622	56.1	0.565**	6.660	2.567**	102.9**	4.315
30 µg/	SD	0.204	1.1	0.197	0.812	0.097	0.9	0.239
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	2.3	-0.9	-70.4	11.9	-9.1	2.0	-1.8
Group 7:	Mean	2.569	55.9	0.507**	7.298	2.632**	103.0**	4.043*
100 µg/	SD	0.225	2.4	0.162	1.831	0.137	1.2	0.283
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	0.2	-1.2	-73.5	22.6	-6.8	2.1	-8.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	2.571 n	55.4 n	0.456 n	8.006 n	2.575 n	99.0 n	3.987 n
	SD	0.163	2.3	0.115	0.595	0.086	1.4	0.223
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a1]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a1]
Group 1: Control	Mean	2.245	53.7	0.413	6.968	2.546	100.6	3.904
	SD	0.295	2.2	0.139	0.751	0.088	1.4	0.390
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	2.658**	54.6	0.509	8.386**	2.621	100.4	4.182
	SD	0.329	1.6	0.163	0.947	0.090	1.7	0.390
	N	10	10	10	10	10	10	10
	%Diff	18.4	1.7	23.2	20.4	2.9	-0.2	7.1
Group 3: 10 µg/ animal BNT162a1	Mean	2.416	53.7	0.540	8.267*	2.512	99.8	3.959
	SD	0.213	2.1	0.073	1.117	0.073	1.2	0.132
	N	10	10	10	10	10	10	10
	%Diff	7.6	0.0	30.8	18.6	-1.3	-0.8	1.4
Group 4: 30 µg/ animal BNT162b1	Mean	2.145	57.3**	0.368	7.457	2.556	100.6	4.141
	SD	0.265	2.1	0.094	1.596	0.098	1.6	0.527
	N	10	10	10	10	10	10	10
	%Diff	-4.5	6.7	-10.9	7.0	0.4	0.0	6.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.324	59.3**	0.545	8.536**	2.579	100.4	4.073
100 µg/	SD	0.286	2.1	0.160	1.115	0.066	1.5	0.391
animal	N	9	10	10	10	10	10	9
BNT162b1	%Diff	3.5	10.4	32.0	22.5	1.3	-0.2	4.3
Group 7:	Mean	2.365	57.9**	0.478	9.437**	2.607	100.1	4.220
100 µg/	SD	0.245	1.6	0.124	1.246	0.068	0.7	0.342
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	5.3	7.8	15.7	35.4	2.4	-0.5	8.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	2.120 n	55.8 n	0.466 n	6.506 n	2.414 n	103.8 n	4.242 n
	SD	0.571	1.3	0.170	0.397	0.083	0.8	0.950
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

FDA-CBER-2021-5683-0766467

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a2]	Potassium (mmol/L) [a]
Group 1: Control	Mean	2.138	56.2	0.498	6.770	2.546	103.2	3.922
	SD	0.150	1.1	0.075	1.318	0.110	0.8	0.229
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	2.192	55.4	0.476	7.182	2.540	102.0	4.068
	SD	0.227	1.7	0.163	0.582	0.082	1.0	0.083
	N	5	5	5	5	5	5	5
	%Diff	2.5	-1.4	-4.4	6.1	-0.2	-1.2	3.7
Group 3: 10 µg/ animal BNT162a1	Mean	2.116	53.4	0.428	7.546	2.482	102.8	3.944
	SD	0.281	1.1	0.158	0.909	0.055	1.3	0.417
	N	5	5	5	5	5	5	5
	%Diff	-1.0	-5.0	-14.1	11.5	-2.5	-0.4	0.6
Group 4: 30 µg/ animal BNT162b1	Mean	2.100	57.0	0.568	7.636	2.464	103.2	3.892
	SD	0.207	2.7	0.070	1.044	0.070	1.3	0.179
	N	5	5	5	5	5	5	5
	%Diff	-1.8	1.4	14.1	12.8	-3.2	0.0	-0.8

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Log)
[a2] - Anova & Dunnett(Rank)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.160	53.4	0.538	7.690	2.502	103.0	4.062
100 µg/	SD	0.288	2.9	0.195	1.256	0.064	1.0	0.136
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	1.0	-5.0	8.0	13.6	-1.7	-0.2	3.6
Group 7:	Mean	2.194	56.8	0.712	7.494	2.522	104.0	4.042
100 µg/	SD	0.116	1.5	0.182	1.460	0.052	1.0	0.167
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	2.6	1.1	43.0	10.7	-0.9	0.8	3.1

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a1]	aP (U/L) [a2]	ASAT (U/L) [a1]	LDH (U/L) [a]	CK (U/L) [a1]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	135.2	66.1	270.2	80.3	90.0	127.2	0.95
	SD	0.8	16.7	53.3	13.4	18.9	26.6	0.87
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	135.4	56.9	257.9	85.1	68.6	176.7	4.21**
	SD	1.0	7.7	32.8	3.9	18.5	72.5	0.96
	N	10	10	10	10	10	10	10
	%Diff	0.1	-13.9	-4.6	6.0	-23.8	38.9	343.2
Group 3: 10 µg/ animal BNT162a1	Mean	136.6**	48.8**	181.8**	99.5**	117.5	120.0	2.93**
	SD	0.8	7.1	50.3	8.5	25.6	93.1	0.51
	N	10	10	10	10	10	10	10
	%Diff	1.0	-26.2	-32.7	23.9	30.6	-5.7	208.4
Group 4: 30 µg/ animal BNT162b1	Mean	135.9	61.9	257.5	77.3	81.5	216.6	2.52**
	SD	0.6	8.7	32.2	6.0	26.0	110.3	0.54
	N	10	10	10	10	10	10	10
	%Diff	0.5	-6.4	-4.7	-3.7	-9.4	70.3	165.3

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	137.3**	45.6**	195.0**	87.0	126.5*	132.7	3.32**
100 µg/	SD	0.7	8.2	27.4	9.3	43.1	96.4	0.65
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	1.6	-31.0	-27.8	8.3	40.6	4.3	249.5
Group 6:	Mean	136.8**	44.2**	189.8**	95.4**	134.9**	152.7	3.60**
30 µg/	SD	0.9	4.0	24.3	6.7	35.0	48.9	1.09
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	1.2	-33.1	-29.8	18.8	49.9	20.0	278.9
Group 7:	Mean	137.3**	44.4**	209.9**	95.9**	138.7**	155.1	3.25**
100 µg/	SD	0.8	9.3	27.2	9.0	39.1	64.8	1.09
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	1.6	-32.8	-22.3	19.4	54.1	21.9	242.1

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6:	Mean	132.1 n	49.5 n	160.3 n	110.4 n	124.6 n	152.6 n	3.98 n
30 µg/	SD	1.4	4.6	13.9	9.9	25.5	53.9	1.12
animal	N	10	10	10	10	10	10	10
BNT162c1		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a1]	LDH (U/L) [a1]	CK (U/L) [a]	Gamma-GT (U/L) [a1]
Group 1: Control	Mean	134.7	35.9	157.2	79.9	109.5	158.0	1.62
	SD	0.9	8.0	25.5	15.6	49.9	106.7	0.76
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	133.8	40.1	190.6*	101.3**	134.0	165.6	4.43**
	SD	2.0	8.2	29.1	12.9	38.8	56.6	0.70
	N	10	10	10	10	10	10	10
	%Diff	-0.7	11.7	21.2	26.8	22.4	4.8	173.5
Group 3: 10 µg/ animal BNT162a1	Mean	133.1*	38.9	133.1	93.8	124.1	124.7	3.04**
	SD	1.1	6.6	28.5	17.3	44.2	22.9	0.90
	N	10	10	10	10	10	10	10
	%Diff	-1.2	8.4	-15.3	17.4	13.3	-21.1	87.7
Group 4: 30 µg/ animal BNT162b1	Mean	134.4	36.2	140.4	88.7	103.4	154.2	3.59**
	SD	1.6	3.2	22.3	8.2	29.5	38.4	0.56
	N	10	10	10	10	10	10	10
	%Diff	-0.2	0.8	-10.7	11.0	-5.6	-2.4	121.6

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05
[a1] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	132.4**	37.9	164.3	85.4	119.6	146.0	4.18**
100 µg/	SD	2.5	13.7	25.3	8.7	24.4	42.1	1.00
animal	N	10	10	10	9	9	10	10
BNT162b1	%Diff	-1.7	5.6	4.5	6.9	9.2	-7.6	158.0
Group 7:	Mean	132.7**	34.0	182.1	89.1	124.3	126.4	4.83**
100 µg/	SD	0.5	6.0	37.1	9.7	20.1	16.3	0.81
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-1.5	-5.3	15.8	11.5	13.5	-20.0	198.1

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	138.4 n	44.0 n	129.8 n	86.2 n	120.4 n	143.4 n	1.84 n
	SD	1.1	6.2	12.9	14.3	24.5	64.4	0.47
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a1]	LDH (U/L) [a1]	CK (U/L) [a1]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	136.6	34.6	110.8	80.4	113.4	305.0	2.60
	SD	0.9	3.0	17.9	20.1	60.0	454.5	0.91
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	135.6	35.4	117.8	78.2	96.6	220.8	2.74
	SD	1.1	3.8	6.9	3.8	42.3	165.0	0.66
	N	5	5	5	5	5	5	5
	%Diff	-0.7	2.3	6.3	-2.7	-14.8	-27.6	5.4
Group 3: 10 µg/ animal BNT162a1	Mean	138.2	37.0	107.6	86.6	132.6	173.6	1.88
	SD	1.1	3.2	24.3	13.2	59.6	131.2	0.54
	N	5	5	5	5	5	5	5
	%Diff	1.2	6.9	-2.9	7.7	16.9	-43.1	-27.7
Group 4: 30 µg/ animal BNT162b1	Mean	137.8	40.4	133.0	87.6	72.4	125.6	2.30
	SD	2.2	3.0	28.5	5.9	44.9	79.5	0.50
	N	5	5	5	5	5	5	5
	%Diff	0.9	16.8	20.0	9.0	-36.2	-58.8	-11.5

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	137.8	40.0	126.4	88.8	105.6	235.6	1.34
100 µg/	SD	1.3	4.1	22.3	14.3	50.4	87.7	0.86
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	0.9	15.6	14.1	10.4	-6.9	-22.8	-48.5
Group 7:	Mean	138.4	39.8	117.4	82.6	74.2	199.8	1.82
100 µg/	SD	0.9	6.5	22.3	10.9	4.1	155.9	0.97
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	1.3	15.0	6.0	2.7	-34.6	-34.5	-30.0

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a2]	Glucose (mmol/L) [a2]
Group 1: Control	Mean	31.61	27.69	1.144	3.51	1.865	43.4	9.037
	SD	1.45	1.71	0.062	0.76	0.309	2.3	0.940
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	27.15**	28.95	0.938**	3.68	1.989	42.1	8.935
	SD	1.06	1.09	0.033	0.65	0.388	1.9	0.737
	N	10	10	10	10	10	10	10
	%Diff	-14.1	4.6	-18.0	4.8	6.6	-3.0	-1.1
Group 3: 10 µg/ animal BNT162a1	Mean	28.03**	25.67	1.095	2.79*	2.062	44.4	6.889**
	SD	1.01	1.82	0.057	0.37	0.275	3.2	1.362
	N	10	10	10	10	10	10	10
	%Diff	-11.3	-7.3	-4.3	-20.5	10.6	2.3	-23.8
Group 4: 30 µg/ animal BNT162b1	Mean	28.97**	30.33*	0.958**	2.57**	1.931	42.6	8.841
	SD	0.93	1.65	0.057	0.40	0.245	1.0	0.731
	N	10	10	10	10	10	10	10
	%Diff	-8.4	9.5	-16.3	-26.8	3.5	-1.8	-2.2

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): * = $p \leq 0.05$; ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Rank): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	28.21**	29.89	0.950**	2.77**	1.865	43.1	7.267
100 µg/	SD	0.69	2.80	0.072	0.37	0.441	3.3	1.698
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-10.8	7.9	-17.0	-21.1	0.0	-0.7	-19.6
Group 6:	Mean	27.92**	27.28	1.028**	3.07	1.948	44.2	7.362*
30 µg/	SD	0.66	2.12	0.072	0.34	0.336	2.1	1.562
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-11.7	-1.5	-10.1	-12.5	4.5	1.8	-18.5
Group 7:	Mean	27.62**	28.68	0.964**	2.73**	1.853	42.8	6.521**
100 µg/	SD	0.97	1.62	0.029	0.39	0.220	2.8	1.059
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-12.6	3.6	-15.7	-22.2	-0.6	-1.4	-27.8

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	27.35 n	26.15 n	1.049 n	3.03 n	1.632 n	46.5 n	8.044 n
	SD	0.64	1.70	0.052	0.20	0.246	3.3	0.582
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a1]	Alb./Glob. Ratio [a2]	Bilirubin (total) (µmol/L) [a]	Choleste-rol (total) (mmol/L) [a]	Crea-tinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 1: Control	Mean	30.36	25.54	1.192	3.03	1.764	46.8	9.502
	SD	1.12	1.57	0.069	0.53	0.389	3.5	0.829
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	27.68**	29.02**	0.962**	4.04**	1.818	47.9	7.820**
	SD	0.84	3.23	0.083	0.55	0.349	2.6	0.873
	N	10	10	10	10	10	10	10
	%Diff	-8.8	13.6	-19.3	33.3	3.1	2.4	-17.7
Group 3: 10 µg/ animal BNT162a1	Mean	27.69**	25.81	1.076	3.61	1.894	49.2	8.533
	SD	0.71	1.50	0.073	0.51	0.384	2.5	1.076
	N	10	10	10	10	10	10	10
	%Diff	-8.8	1.1	-9.7	19.1	7.4	5.1	-10.2
Group 4: 30 µg/ animal BNT162b1	Mean	27.38**	30.12**	0.910**	3.06	1.448	47.2	8.614
	SD	1.04	1.72	0.037	0.57	0.284	1.8	1.551
	N	10	10	10	10	10	10	10
	%Diff	-9.8	17.9	-23.6	1.0	-17.9	0.9	-9.3

[a] - Anova & Dunnett: ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a2] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	27.17**	29.23**	0.933**	3.83*	1.444	49.3	8.167*
100 µg/	SD	1.05	2.34	0.054	0.72	0.322	2.6	1.046
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-10.5	14.4	-21.7	26.4	-18.1	5.3	-14.0
Group 7:	Mean	27.03**	30.07**	0.901**	3.96*	1.305*	50.2*	8.487
100 µg/	SD	0.69	1.68	0.044	0.97	0.159	3.1	1.241
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-11.0	17.7	-24.4	30.7	-26.0	7.3	-10.7

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	31.10 n	28.50 n	1.092 n	3.46 n	1.640 n	52.8 n	9.506 n
	SD	1.53	1.38	0.041	0.57	0.498	4.2	0.880
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a1]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a1]	Glucose (mmol/L) [a]
Group 1: Control	Mean	31.26	29.54	1.058	2.78	1.878	55.2	9.136
	SD	2.25	0.55	0.077	0.19	0.453	2.9	1.348
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	30.96	30.64	1.011	3.38	1.952	52.4	8.822
	SD	1.90	1.69	0.051	1.07	0.638	3.8	1.369
	N	5	5	5	5	5	5	5
	%Diff	-1.0	3.7	-4.5	21.6	3.9	-5.1	-3.4
Group 3: 10 µg/ animal BNT162a1	Mean	29.76	23.84**	1.251**	3.26	1.626	51.0	9.618
	SD	0.56	1.30	0.069	0.30	0.342	1.7	1.414
	N	5	5	5	5	5	5	5
	%Diff	-4.8	-19.3	18.2	17.3	-13.4	-7.6	5.3
Group 4: 30 µg/ animal BNT162b1	Mean	30.80	30.00	1.029	3.00	1.780	54.8	10.114
	SD	0.79	1.71	0.053	0.39	0.124	3.7	1.512
	N	5	5	5	5	5	5	5
	%Diff	-1.5	1.6	-2.8	7.9	-5.2	-0.7	10.7

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Albumin (g/L) [a]	Globulin (g/L) [a]	Alb./Glob. Ratio [a]	Bilirubin (total) (µmol/L) [a]	Cholesterol (total) (mmol/L) [a]	Creatinine (µmol/L) [a]	Glucose (mmol/L) [a]
Group 5:	Mean	30.88	27.72	1.118	3.14	1.804	55.2	10.164
100 µg/	SD	1.97	2.85	0.067	0.54	0.596	5.9	2.126
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	-1.2	-6.2	5.7	12.9	-3.9	0.0	11.3
Group 7:	Mean	30.50	27.10	1.132	2.86	2.038	51.2	9.334
100 µg/	SD	0.96	2.03	0.115	0.33	0.321	2.9	2.048
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	-2.4	-8.3	7.0	2.9	8.5	-7.2	2.2

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 1: Control	Mean	2.207	59.3	1.560	6.913	2.770	102.2	4.244
	SD	0.225	2.8	0.602	0.943	0.089	1.2	0.257
	N	10	10	10	10	10	10	10
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	2.487*	56.1*	1.846	6.966	2.815	100.7**	4.118
	SD	0.183	1.9	0.538	0.775	0.064	1.1	0.190
	N	10	10	10	10	10	10	10
	%Diff	12.7	-5.4	18.3	0.8	1.6	-1.5	-3.0
Group 3: 10 µg/ animal BNT162a1	Mean	2.278	53.7**	0.521**	6.622	2.640**	103.3	3.844*
	SD	0.231	2.6	0.109	1.299	0.104	0.8	0.216
	N	10	10	10	10	10	10	10
	%Diff	3.2	-9.4	-66.6	-4.2	-4.7	1.1	-9.4
Group 4: 30 µg/ animal BNT162b1	Mean	2.329	59.3	0.906**	6.964	2.818	101.7	4.226
	SD	0.110	1.9	0.334	0.795	0.083	0.9	0.309
	N	10	10	10	10	10	10	10
	%Diff	5.5	0.0	-41.9	0.7	1.7	-0.5	-0.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.321	58.1	0.534**	6.604	2.724	103.3	4.040
100 µg/	SD	0.234	3.3	0.211	1.059	0.115	0.8	0.381
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	5.2	-2.0	-65.8	-4.5	-1.7	1.1	-4.8
Group 6:	Mean	2.536**	55.2**	0.678**	6.935	2.709	102.5	4.006
30 µg/	SD	0.236	2.5	0.248	1.262	0.085	1.0	0.214
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	14.9	-6.9	-56.5	0.3	-2.2	0.3	-5.6
Group 7:	Mean	2.355	56.3	0.441**	6.147	2.694	103.3	3.980
100 µg/	SD	0.167	2.5	0.187	0.594	0.072	1.2	0.316
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	6.7	-5.1	-71.7	-11.1	-2.7	1.1	-6.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	2.236 n	53.5 n	0.453 n	8.592 n	2.597 n	100.2 n	4.019 n
	SD	0.167	2.2	0.105	0.687	0.087	1.8	0.285
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 1: Control	Mean	1.845	55.9	0.340	7.863	2.574	101.9	3.590
	SD	0.300	2.2	0.095	1.373	0.111	1.0	0.336
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	2.246**	56.7	0.475*	7.850	2.666	100.8	3.899
	SD	0.237	3.8	0.136	1.322	0.100	1.7	0.259
	N	10	10	10	10	10	10	10
	%Diff	21.7	1.4	39.7	-0.2	3.6	-1.1	8.6
Group 3: 10 µg/ animal BNT162a1	Mean	2.043	53.5	0.603**	8.094	2.587	102.3	3.996*
	SD	0.228	1.6	0.225	1.122	0.104	1.2	0.190
	N	10	10	10	10	10	10	10
	%Diff	10.7	-4.3	77.4	2.9	0.5	0.4	11.3
Group 4: 30 µg/ animal BNT162b1	Mean	2.124	57.5	0.357	8.105	2.663	101.3	3.902
	SD	0.272	2.6	0.070	0.857	0.099	0.8	0.246
	N	10	10	10	10	10	10	10
	%Diff	15.1	2.9	5.0	3.1	3.5	-0.6	8.7

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	2.088	56.4	0.444	8.453	2.640	101.4	4.180**
100 µg/	SD	0.347	3.3	0.104	1.284	0.084	1.3	0.378
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	13.2	0.9	30.6	7.5	2.6	-0.5	16.4
Group 7:	Mean	2.039	57.1	0.450	8.324	2.685	102.4	3.954*
100 µg/	SD	0.202	2.1	0.109	1.162	0.076	1.3	0.346
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	10.5	2.1	32.4	5.9	4.3	0.5	10.1

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.700 n	59.6 n	0.396 n	7.398 n	2.522 n	102.2 n	3.530 n
	SD	0.209	2.7	0.146	1.166	0.086	0.8	0.126
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a1]	Tri-glycerides (mmol/L) [a1]	Urea (in blood) (mmol/L) [a1]	Calcium (mmol/L) [a1]	Chloride (mmol/L) [a1]	Potassium (mmol/L) [a1]
Group 1: Control	Mean	1.630	60.8	0.408	8.010	2.584	103.2	3.504
	SD	0.192	2.4	0.107	0.743	0.078	1.8	0.347
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	1.786	61.6	0.406	7.682	2.546	103.6	3.426
	SD	0.153	3.2	0.053	1.402	0.068	1.5	0.336
	N	5	5	5	5	5	5	5
	%Diff	9.6	1.3	-0.5	-4.1	-1.5	0.4	-2.2
Group 3: 10 µg/ animal BNT162a1	Mean	1.830	53.6**	0.418	8.366	2.476	102.4	3.750
	SD	0.196	1.5	0.071	0.562	0.056	1.1	0.120
	N	5	5	5	5	5	5	5
	%Diff	12.3	-11.8	2.5	4.4	-4.2	-0.8	7.0
Group 4: 30 µg/ animal BNT162b1	Mean	1.780	60.8	0.348	8.390	2.586	103.2	3.574
	SD	0.065	2.2	0.073	0.946	0.088	0.8	0.304
	N	5	5	5	5	5	5	5
	%Diff	9.2	0.0	-14.7	4.7	0.1	0.0	2.0

[a] - Anova & Dunnett(Rank)
[a1] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Phosphate (mmol/L) [a]	Protein (total) (g/L) [a]	Tri-glycerides (mmol/L) [a]	Urea (in blood) (mmol/L) [a]	Calcium (mmol/L) [a]	Chloride (mmol/L) [a]	Potassium (mmol/L) [a]
Group 5:	Mean	1.776	58.6	0.484	7.230	2.490	102.6	3.522
100 µg/	SD	0.403	4.6	0.208	1.054	0.130	0.9	0.319
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	9.0	-3.6	18.6	-9.7	-3.6	-0.6	0.5
Group 7:	Mean	1.908	57.6	0.396	7.528	2.510	103.2	3.580
100 µg/	SD	0.416	1.8	0.081	0.733	0.111	1.5	0.418
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	17.1	-5.3	-2.9	-6.0	-2.9	0.0	2.2

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a1]	aP (U/L) [a1]	ASAT (U/L) [a1]	LDH (U/L) [a2]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	135.8	57.3	154.2	74.5	86.1	118.0	0.88
	SD	1.0	7.6	24.9	19.2	18.8	44.8	0.59
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	135.0	59.1	198.0**	85.8	68.7	133.6	3.67**
	SD	1.2	7.4	35.9	10.7	10.0	79.3	1.10
	N	10	10	10	10	10	10	10
	%Diff	-0.6	3.1	28.4	15.2	-20.2	13.2	317.0
Group 3: 10 µg/ animal BNT162a1	Mean	136.8	45.5*	141.7	98.8**	120.3	153.4	2.75**
	SD	1.0	9.7	20.2	9.8	48.7	112.3	0.54
	N	10	10	10	10	10	10	10
	%Diff	0.7	-20.6	-8.1	32.6	39.7	30.0	212.5
Group 4: 30 µg/ animal BNT162b1	Mean	135.4	49.0	167.7	75.8	67.6	129.7	2.32
	SD	0.8	13.0	22.3	11.6	13.9	71.8	1.01
	N	10	10	10	10	10	10	10
	%Diff	-0.3	-14.5	8.8	1.7	-21.5	9.9	163.6

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a2] - Anova & Dunnett(Log)

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	136.7	40.1**	150.6	90.7*	125.0*	119.0	3.72**
100 µg/	SD	1.1	7.6	25.7	10.4	44.3	140.6	1.48
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	0.7	-30.0	-2.3	21.7	45.2	0.8	322.7
Group 6:	Mean	135.7	52.1	151.5	107.2**	142.9**	136.7	3.77**
30 µg/	SD	0.9	9.5	25.9	9.9	38.5	130.2	0.78
animal	N	10	10	10	10	10	10	10
BNT162c1	%Diff	-0.1	-9.1	-1.8	43.9	66.0	15.8	328.4
Group 7:	Mean	136.8	36.4**	161.3	96.6**	133.3*	106.1	4.01**
100 µg/	SD	1.5	7.7	24.5	13.8	49.2	69.8	0.85
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	0.7	-36.5	4.6	29.7	54.8	-10.1	355.7

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	132.3 n	58.1 n	141.7 n	122.5 n	108.6 n	122.2 n	4.26 n
	SD	2.0	27.4	32.1	15.8	18.1	23.4	0.79
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a1]	ASAT (U/L) [a1]	LDH (U/L) [a1]	CK (U/L) [a]	Gamma-GT (U/L) [a1]
Group 1: Control	Mean	134.9	34.2	75.9	80.6	125.3	106.6	1.21
	SD	0.7	7.0	11.7	10.6	40.6	31.1	0.59
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	133.1*	57.8**	155.9**	118.7**	141.7	175.7	3.97**
	SD	1.1	26.2	23.2	21.8	40.2	131.6	0.72
	N	10	10	10	10	10	10	10
	%Diff	-1.3	69.0	105.4	47.3	13.1	64.8	228.1
Group 3: 10 µg/ animal BNT162a1	Mean	134.1	37.9	120.5**	95.3	155.9	182.3	3.32**
	SD	1.7	5.9	25.5	12.6	26.7	125.9	1.33
	N	10	10	10	10	10	10	10
	%Diff	-0.6	10.8	58.8	18.2	24.4	71.0	174.4
Group 4: 30 µg/ animal BNT162b1	Mean	133.4	34.3	108.7*	86.4	104.6	165.0	3.94**
	SD	1.3	6.4	24.5	13.0	38.7	107.7	1.10
	N	10	10	10	10	10	10	10
	%Diff	-1.1	0.3	43.2	7.2	-16.5	54.8	225.6

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	132.6**	33.4	158.9**	102.7**	147.4	183.7	4.40**
100 µg/	SD	2.1	6.8	29.6	9.9	40.1	92.6	0.61
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	-1.7	-2.3	109.4	27.4	17.6	72.3	263.6
Group 7:	Mean	133.8	30.8	183.8**	100.2*	155.4	139.6	5.05**
100 µg/	SD	1.9	6.7	24.6	12.5	61.5	31.8	0.88
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-0.8	-9.9	142.2	24.3	24.0	31.0	317.4

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 6:	Mean	136.4 n	32.0 n	68.4 n	86.6 n	118.0 n	250.6 n	2.14 n
30 µg/	SD	1.1	10.0	14.0	24.7	13.6	255.4	0.33
animal	N	5	5	5	5	5	5	5
BNT162c1		-	-	-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a1]	aP (U/L) [a1]	ASAT (U/L) [a2]	LDH (U/L) [a2]	CK (U/L) [a2]	Gamma-GT (U/L) [a]
Group 1: Control	Mean	136.8	35.4	61.4	79.2	69.4	120.2	2.48
	SD	2.4	7.1	13.3	7.6	37.5	45.2	0.76
	N	5	5	5	5	5	5	5
	-							
Group 2: 30 µg/ animal BNT162a1	Mean	137.4	40.6	67.4	94.8	90.0	205.0	3.06
	SD	2.1	20.0	20.8	45.7	72.9	263.1	0.65
	N	5	5	5	5	5	5	5
	%Diff	0.4	14.7	9.8	19.7	29.7	70.5	23.4
Group 3: 10 µg/ animal BNT162a1	Mean	136.0	32.4	72.4	79.4	132.6	315.4	1.74
	SD	1.0	4.2	7.5	14.0	38.1	368.0	0.86
	N	5	5	5	5	5	5	5
	%Diff	-0.6	-8.5	17.9	0.3	91.1	162.4	-29.8
Group 4: 30 µg/ animal BNT162b1	Mean	136.6	30.4	64.6	84.6	100.2	208.4	2.52
	SD	0.5	7.3	2.5	15.3	53.1	101.2	0.67
	N	5	5	5	5	5	5	5
	%Diff	-0.1	-14.1	5.2	6.8	44.4	73.4	1.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)
[a2] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0766500

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TABLE 7-1 Biochemical Parameters - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Biochemical Parameters						
		Sodium (mmol/L) [a]	ALAT (U/L) [a]	aP (U/L) [a]	ASAT (U/L) [a]	LDH (U/L) [a]	CK (U/L) [a]	Gamma-GT (U/L) [a]
Group 5:	Mean	137.0	35.4	64.8	85.4	108.4	165.4	2.12
100 µg/	SD	0.7	3.4	14.3	20.3	60.2	108.1	0.64
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	0.1	0.0	5.5	7.8	56.2	37.6	-14.5
Group 7:	Mean	137.8	31.6	67.0	82.2	89.0	151.8	2.44
100 µg/	SD	1.6	5.4	5.1	10.7	49.4	59.4	0.66
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	0.7	-10.7	9.1	3.8	28.2	26.3	-1.6

[a] - Anova & Dunnett

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Male	Cholesterol (total)	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Bilirubin (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Creatinine	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Glucose	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	4	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Cholesterol (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Creatinine	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Globulin	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Cholesterol (total)	*	Anova & Dunnett: * = p ≤ 0.05
	4	6	Male	Creatinine	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Globulin	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	7	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Cholesterol (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Creatinine	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Male	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Cholesterol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Creatinine	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Bilirubin (total)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Cholesterol (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Bilirubin (total)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Cholesterol (total)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	4	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Cholesterol (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	5	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Cholesterol (total)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Male	Crea- tinine	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Choleste- rol (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Crea- tinine	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	38	4	Male	Crea- tinine	**	Anova & Dunnett: ** = p ≤ 0.01

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Chloride	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Potassium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	Phosphate	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	4	4	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Potassium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	10	6	Male	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Phosphate	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Urea	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Urea	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	4	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	5	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Urea	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Urea	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Male	ALAT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	aP	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Male	ASAT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Lactate Dehy drogenase	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Lactate Dehy drogenase	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Lactate Dehy drogenase	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	aP	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	2	Male	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Sodium	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	3	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Bilirubin (total)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	4	3	Female	Glucose	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	4	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Globulin	*	Anova & Dunnett: * = p ≤ 0.05
	4	4	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Bilirubin (total)	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Glucose	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	2	Female	Alb./Glob. Ratio	**	Anova & Dunnett(Rank): ** = p ≤ 0.01

FDA-CBER-2021-5683-0766509

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Bilirubin (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Glucose	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Globulin	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	4	Female	Alb./Glob. Ratio	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Bilirubin (total)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Glucose	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Albumin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Bilirubin (total)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Choleste- rol (total)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Crea- tinine	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	Albumin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Globulin	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Alb./Glob. Ratio	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Bilirubin (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Choleste- rol (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Crea- tinine	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Glucose	n	Anova & Dunnett: n - Inappropriate for statistics
	38	3	Female	Globulin	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	Alb./Glob. Ratio	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Phosphate	*	Anova & Dunnett: * = p ≤ 0.05
	4	2	Female	Protein (total)	*	Anova & Dunnett: * = p ≤ 0.05
	4	2	Female	Chloride	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Female	Calcium	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	4	4	Female	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Phosphate	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Protein (total)	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Tri- glycerides	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Phosphate	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Tri- glycerides	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	3	Female	Tri- glycerides	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Female	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Potassium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Potassium	*	Anova & Dunnett: * = p ≤ 0.05
	31	6	Female	Phosphate	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Protein (total)	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Tri- glycerides	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	31	6	Female	Urea	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Calcium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Chloride	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Potassium	n	Anova & Dunnett: n - Inappropriate for statistics
	38	3	Female	Protein (total)	**	Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Gamma-GT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Female	ALAT	*	Anova & Dunnett: * = p ≤ 0.05
	4	3	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Gamma-GT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	5	Female	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	ASAT	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Female	Lactate Dehy drogenase	*	Anova & Dunnett: * = p ≤ 0.05
	4	5	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Lactate Dehy drogenase	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	ALAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Lactate Dehy drogenase	*	Anova & Dunnett: * = p ≤ 0.05
	4	7	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Sodium	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	2	Female	ALAT	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 7-1 Biochemical Parameters - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	3	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	aP	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Sodium	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	ASAT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	aP	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	ASAT	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Gamma-GT	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	Sodium	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	ALAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	aP	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	ASAT	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Lactate Dehy drogenase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Creatine Kinase	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Gamma-GT	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
1	28.6	25.4	1.13	3.2	1.54	39	9.22
2	29.4	26.6	1.11	3.0	2.05	38	8.95
3	30.1	27.9	1.08	4.7	2.03	40	8.55
4	29.6	27.4	1.08	4.7	2.30	45	9.42
5	30.1	26.9	1.12	4.0	2.54	40	8.61
11	29.4	27.6	1.07	2.6	1.54	39	9.74
12	28.5	27.5	1.04	3.9	1.94	39	10.16
13	30.5	27.5	1.11	4.0	2.37	40	8.85
14	29.8	27.2	1.10	3.8	1.46	39	9.41
15	28.8	27.2	1.06	3.2	2.05	37	8.51
Mean	29.48	27.12	1.087	3.71	1.982	39.6	9.142
SD	0.68	0.71	0.029	0.70	0.371	2.1	0.548
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
31	27.2	29.8	0.91	2.8	1.47	41	8.96
32	26.1	29.9	0.87	3.7	1.07	35	8.63
33	26.5	26.5	1.00	3.0	1.94	37	9.26
34	26.9	29.1	0.92	3.7	1.31	36	8.77
35	26.6	30.4	0.88	3.9	1.36	41	9.25
41	27.2	30.8	0.88	2.9	1.65	39	8.63
42	27.0	31.0	0.87	3.0	1.42	36	10.02
43	26.1	28.9	0.90	3.7	1.95	36	9.27
44	26.9	32.1	0.84	2.6	2.20	37	8.29
45	26.5	28.5	0.93	3.1	1.74	38	8.65
Mean	26.70	29.70	0.901	3.24	1.611	37.6	8.973
SD	0.41	1.56	0.045	0.46	0.348	2.1	0.493
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
61	26.7	27.3	0.98	2.5	1.82	41	6.40
62	27.6	27.4	1.01	2.2	1.88	48	5.50
63	26.2	25.8	1.02	2.1	1.52	42	5.93
64	27.4	29.6	0.93	2.8	1.58	42	7.50
65	28.3	27.7	1.02	3.3	1.85	42	5.86
71	27.6	28.4	0.97	3.1	1.25	40	6.85
72	27.0	28.0	0.96	3.1	1.97	45	6.19
73	27.5	27.5	1.00	2.6	2.18	44	6.17
74	28.3	27.7	1.02	2.8	1.56	42	7.19
75	28.2	26.8	1.05	2.7	1.69	46	5.65
Mean	27.48	27.62	0.996	2.72	1.730	43.2	6.324
SD	0.70	0.99	0.036	0.39	0.265	2.5	0.663
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
91	27.6	31.4	0.88	3.4	1.54	40	8.08
92	27.7	29.3	0.95	2.7	1.23	39	8.15
93	28.0	31.0	0.90	3.0	1.55	39	8.58
94	29.0	36.0	0.81	3.6	1.73	39	8.11
95	28.4	31.6	0.90	3.9	1.76	39	9.10
101	28.6	30.4	0.94	3.4	1.50	43	8.89
102	29.4	33.6	0.88	3.5	1.94	39	8.80
103	27.5	30.5	0.90	2.5	2.02	39	8.34
104	28.1	29.9	0.94	3.0	1.71	42	9.38
105	28.4	30.6	0.93	3.6	1.49	38	8.67
Mean	28.27	31.43	0.902	3.26	1.647	39.7	8.610
SD	0.62	1.98	0.042	0.44	0.233	1.6	0.443
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
121	28.2	28.8	0.98	3.0	1.35	47	6.06
122	26.9	29.1	0.92	2.5	0.93	38	7.00
123	27.1	31.9	0.85	2.9	2.07	42	4.83
124	27.9	31.1	0.90	2.2	1.73	45	5.42
125	27.6	27.4	1.01	2.8	1.22	47	5.79
131	27.3	29.7	0.92	2.8	1.33	45	5.97
132	28.2	32.8	0.86	2.9	1.97	45	6.04
133	26.1	26.9	0.97	2.5	1.24	40	5.94
134	27.5	29.5	0.93	2.6	1.46	41	6.45
135	27.3	28.7	0.95	2.8	1.28	45	7.24
Mean	27.41	29.59	0.929	2.70	1.458	43.5	6.074
SD	0.63	1.87	0.051	0.24	0.358	3.1	0.703
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
151	27.3	29.7	0.92	2.7	1.98	45	6.24
152	27.4	27.6	0.99	2.6	1.79	43	7.46
153	27.0	30.0	0.90	2.7	1.71	46	5.58
154	27.9	28.1	0.99	3.0	1.49	43	6.00
155	27.2	30.8	0.88	2.6	1.50	42	5.75
161	26.6	28.4	0.94	2.3	1.82	31	7.79
162	26.5	28.5	0.93	2.3	1.63	42	6.13
163	27.6	28.4	0.97	2.9	1.39	46	7.38
164	27.6	29.4	0.94	2.8	1.39	46	8.80
165	27.1	27.9	0.97	2.5	1.28	41	7.24
Mean	27.22	28.88	0.944	2.64	1.598	42.5	6.837
SD	0.44	1.04	0.038	0.23	0.225	4.5	1.050
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
181	26.7	30.3	0.88	2.7	1.45	44	6.30
182	27.8	31.2	0.89	2.6	1.50	45	10.82
183	27.6	30.4	0.91	2.5	1.48	42	9.75
184	25.7	27.3	0.94	3.4	1.78	55	5.18
185	27.4	28.6	0.96	2.8	1.63	39	5.93
191	25.0	28.0	0.89	2.6	1.38	40	5.44
192	26.6	26.4	1.01	2.6	1.00	39	5.14
193	27.2	27.8	0.98	2.5	1.42	44	5.87
194	26.9	32.1	0.84	3.3	1.39	45	6.65
195	27.0	29.0	0.93	2.8	1.75	43	6.45
Mean	26.79	29.11	0.923	2.78	1.478	43.6	6.753
SD	0.86	1.83	0.051	0.32	0.221	4.6	1.946
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
151	27.5	28.5	0.96	3.1	1.38	42	9.19
152	28.3	29.7	0.95	3.0	1.22	53	10.89
153	28.0	30.0	0.93	2.6	1.61	46	8.04
154	28.0	27.0	1.04	3.7	1.14	47	7.94
155	27.0	29.0	0.93	2.8	1.26	43	9.30
156	27.9	30.1	0.93	3.3	1.31	40	7.41
157	27.8	27.2	1.02	3.4	1.08	48	10.06
158	26.7	27.3	0.98	3.1	0.88	40	8.09
159	25.6	26.4	0.97	2.6	1.19	44	9.08
160	26.4	25.6	1.03	3.6	1.20	43	8.40
Mean	27.32	28.08	0.975	3.12	1.227	44.6	8.840
SD	0.87	1.60	0.042	0.39	0.191	4.0	1.072
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
1	29.1	25.9	1.12	2.7	1.33	42	9.92
2	28.7	24.3	1.18	2.4	1.72	47	10.93
3	28.7	28.3	1.01	2.0	1.69	48	10.07
4	28.6	25.4	1.13	2.3	2.03	47	8.77
5	29.8	25.2	1.18	2.3	2.46	43	7.56
6	28.1	25.9	1.08	2.1	1.99	47	7.31
7	29.1	25.9	1.12	2.4	2.44	43	9.40
8	26.5	23.5	1.13	2.9	1.92	49	10.03
9	26.5	23.5	1.13	2.3	1.90	48	11.16
10	28.3	25.7	1.10	2.4	1.46	46	10.02
Mean	28.34	25.36	1.119	2.38	1.894	46.0	9.517
SD	1.08	1.40	0.048	0.26	0.369	2.4	1.289
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
31	27.2	27.8	0.98	3.3	1.23	46	7.75
32	26.8	29.2	0.92	3.0	0.98	47	5.81
33	27.2	28.8	0.94	3.0	1.23	42	8.58
34	26.7	27.3	0.98	3.6	0.96	45	9.28
35	26.3	26.7	0.99	3.5	1.20	44	9.60
36	27.9	29.1	0.96	3.6	1.86	54	8.70
37	26.9	28.1	0.96	2.9	0.81	53	8.07
38	25.6	26.4	0.97	3.4	0.96	43	7.78
39	26.6	28.4	0.94	3.4	1.31	48	8.93
40	26.6	26.4	1.01	3.7	1.30	48	8.13
Mean	26.78	27.82	0.963	3.34	1.184	47.0	8.263
SD	0.61	1.08	0.026	0.28	0.293	4.0	1.061
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
61	26.6	27.4	0.97	3.2	1.48	48	8.34
62	28.1	27.9	1.01	2.6	1.61	52	7.49
63	25.5	25.5	1.00	3.4	1.18	49	7.83
64	26.7	29.3	0.91	3.0	1.48	48	9.64
65	27.4	26.6	1.03	2.7	1.32	49	8.88
66	27.1	27.9	0.97	3.8	1.29	48	7.25
67	25.5	24.5	1.04	3.3	1.53	46	8.39
68	27.3	27.7	0.99	2.6	1.68	49	8.59
69	26.5	27.5	0.96	3.4	1.87	45	7.59
70	26.0	26.0	1.00	3.3	1.41	50	9.85
Mean	26.67	27.03	0.988	3.13	1.485	48.4	8.385
SD	0.84	1.39	0.037	0.40	0.202	2.0	0.884
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
91	26.3	28.7	0.92	3.1	1.10	46	8.49
92	27.2	26.8	1.01	2.2	1.07	47	9.02
93	26.6	29.4	0.90	2.8	1.07	46	7.40
94	28.5	32.5	0.88	2.7	1.12	48	8.59
95	26.6	29.4	0.90	2.8	1.13	50	8.47
96	27.9	29.1	0.96	3.1	1.01	44	9.38
97	27.6	30.4	0.91	3.1	1.06	49	10.63
98	27.3	31.7	0.86	2.8	1.09	50	7.82
99	27.0	31.0	0.87	3.0	1.11	46	7.83
100	27.3	31.7	0.86	3.0	1.59	45	9.34
Mean	27.23	30.07	0.908	2.86	1.135	47.1	8.697
SD	0.66	1.72	0.048	0.28	0.164	2.1	0.945
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
121	28.2	30.8	0.92	3.9	1.08	53	6.01
122	27.0	30.0	0.90	3.5	0.79	46	7.66
123	26.4	31.6	0.84	3.1	1.67	51	7.87
124	26.5	33.5	0.79	2.5	1.15	47	8.61
125	26.2	29.8	0.88	3.0	1.33	52	8.45
126	27.3	31.7	0.86	3.2	1.29	55	8.82
127	27.8	31.2	0.89	3.2	1.46	49	10.62
128	27.5	32.5	0.85	3.5	1.45	50	8.56
129	27.9	35.1	0.79	3.6	1.47	55	7.10
130	27.8	34.2	0.81	5.3	1.29	48	7.95
Mean	27.26	32.04	0.853	3.48	1.298	50.6	8.165
SD	0.70	1.77	0.044	0.75	0.246	3.2	1.205
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
181	26.6	30.4	0.88	3.0	1.14	53	9.45
182	27.0	30.0	0.90	3.9	1.47	57	7.51
183	27.1	33.9	0.80	3.4	1.35	52	10.14
184	26.5	30.5	0.87	3.1	1.25	56	8.01
185	26.0	31.0	0.84	2.8	1.37	51	9.16
186	27.1	32.9	0.82	3.5	1.09	53	8.80
187	26.7	31.3	0.85	3.8	1.20	49	7.92
188	27.3	31.7	0.86	3.5	1.24	52	10.13
189	26.6	30.4	0.88	3.7	1.23	46	9.54
190	25.9	30.1	0.86	3.3	1.56	46	8.64
Mean	26.68	31.22	0.856	3.40	1.290	51.5	8.930
SD	0.47	1.29	0.029	0.36	0.147	3.7	0.918
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
161	28.8	28.2	1.02	3.1	1.44	49	9.70
162	26.9	28.1	0.96	3.0	1.62	51	9.23
163	27.6	26.4	1.05	3.2	1.51	47	9.46
164	28.3	28.7	0.99	3.0	1.53	53	5.93
165	28.0	28.0	1.00	2.9	1.49	49	10.98
Mean	27.92	27.88	1.002	3.04	1.518	49.8	9.060
SD	0.72	0.87	0.034	0.11	0.066	2.3	1.876
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
11	29.5	27.5	1.07	3.1	1.28	49	12.51
12	28.3	26.7	1.06	3.7	1.47	48	7.21
13	28.9	28.1	1.03	3.1	1.73	52	13.33
14	30.0	27.0	1.11	2.7	1.33	46	9.47
15	27.7	27.3	1.01	2.2	1.58	45	7.42
Mean	28.88	27.32	1.057	2.96	1.478	48.0	9.988
SD	0.92	0.53	0.038	0.55	0.184	2.7	2.833
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
41	29.5	28.5	1.04	3.9	1.89	48	8.57
42	28.5	26.5	1.08	2.7	1.09	46	13.02
43	27.2	26.8	1.01	2.4	1.81	52	10.36
44	28.2	27.8	1.01	3.1	2.23	49	9.66
45	28.8	25.2	1.14	3.4	1.51	49	10.49
Mean	28.44	26.96	1.057	3.10	1.706	48.8	10.420
SD	0.84	1.27	0.054	0.59	0.429	2.2	1.641
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
71	29.8	24.2	1.23	3.4	1.48	52	9.97
72	28.3	24.7	1.15	3.0	1.58	47	9.98
73	27.4	25.6	1.07	3.0	2.03	48	9.77
74	27.8	24.2	1.15	2.4	1.80	49	10.89
75	28.7	26.3	1.09	2.9	1.43	48	11.91
Mean	28.40	25.00	1.137	2.94	1.664	48.8	10.504
SD	0.92	0.92	0.063	0.36	0.249	1.9	0.898
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
101	29.0	27.0	1.07	3.1	1.41	54	11.07
102	28.5	30.5	0.93	2.5	1.77	54	10.38
103	27.4	29.6	0.93	2.2	2.15	54	8.69
104	29.1	30.9	0.94	2.7	1.91	53	8.33
105	27.7	25.3	1.09	2.2	1.85	51	10.50
Mean	28.34	28.66	0.994	2.54	1.818	53.2	9.794
SD	0.76	2.42	0.083	0.38	0.269	1.3	1.207
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
131	28.0	28.0	1.00	2.9	1.38	50	9.82
132	28.9	23.1	1.25	2.4	1.76	53	10.51
133	27.5	23.5	1.17	2.5	1.76	54	12.17
134	29.5	27.5	1.07	2.9	1.80	47	7.76
135	28.4	22.6	1.26	3.1	1.53	46	11.15
Mean	28.46	24.94	1.150	2.76	1.646	50.0	10.282
SD	0.78	2.59	0.112	0.30	0.183	3.5	1.654
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
191	28.5	30.5	0.93	2.7	2.01	49	8.71
192	29.8	27.2	1.10	3.0	1.73	46	8.65
193	29.5	27.5	1.07	3.0	2.10	50	10.43
194	29.0	27.0	1.07	2.8	1.50	50	8.17
195	28.9	26.1	1.11	2.9	2.20	48	9.08
Mean	29.14	27.66	1.057	2.88	1.908	48.6	9.008
SD	0.51	1.67	0.070	0.13	0.288	1.7	0.858
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
1	2.60	54	1.25	6.59	2.77	101	4.34
2	2.79	56	1.54	5.82	2.74	100	4.31
3	2.65	58	2.54	7.06	2.90	100	4.02
4	2.41	57	3.33	4.78	2.87	101	4.72
5	2.44	57	1.63	6.41	2.83	100	4.65
11	2.62	57	1.38	4.85	2.80	101	3.79
12	2.71	56	1.55	7.05	2.74	102	4.49
13	2.50	58	2.58	5.56	2.88	102	4.29
14	2.24	57	1.42	6.30	2.85	101	4.64
15	2.67	56	1.89	5.12	2.86	101	4.68
Mean	2.563	56.6	1.911	5.954	2.824	100.9	4.393
SD	0.165	1.2	0.680	0.858	0.058	0.7	0.307
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
31	2.60	57	0.80	7.45	2.76	102	4.45
32	2.61	56	1.28	6.11	2.79	101	4.50
33	2.50	53	1.36	6.06	2.89	100	4.12
34	2.62	56	1.55	6.55	2.84	101	4.10
35	2.68	57	1.26	6.75	2.70	100	4.67
41	2.54	58	0.61	6.80	2.87	102	4.62
42	2.47	58	0.78	6.97	2.92	100	4.85
43	2.42	55	1.77	6.98	2.70	102	4.85
44	2.50	59	1.23	6.19	2.69	100	4.39
45	2.61	55	0.63	6.84	2.82	102	4.23
Mean	2.555	56.4	1.127	6.670	2.798	101.0	4.478
SD	0.081	1.8	0.400	0.444	0.084	0.9	0.274
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
61	3.04	54	0.44	6.26	2.68	101	4.14
62	2.59	55	0.52	4.77	2.64	103	4.05
63	2.63	52	0.39	7.36	2.49	102	3.80
64	2.60	57	0.64	8.01	2.60	102	4.15
65	2.70	56	0.90	6.78	2.66	103	3.98
71	2.72	56	0.37	9.46	2.54	102	4.07
72	2.66	55	0.63	8.65	2.64	102	3.79
73	2.56	55	0.72	5.98	2.68	101	3.95
74	2.73	56	0.44	8.69	2.66	102	4.26
75	2.72	55	0.68	8.36	2.76	103	3.65
Mean	2.695	55.1	0.573	7.432	2.635	102.1	3.984
SD	0.136	1.4	0.170	1.467	0.076	0.7	0.190
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
91	2.52	59	1.11	6.35	2.84	101	4.34
92	2.44	57	1.31	5.45	2.76	101	4.20
93	2.32	59	1.23	6.80	2.83	102	4.49
94	2.51	65	1.96	7.20	2.94	100	4.74
95	2.24	60	1.88	6.25	2.86	101	4.27
101	2.22	59	1.34	6.47	2.80	102	4.22
102	2.52	63	2.04	8.19	2.93	100	4.09
103	2.23	58	1.04	5.98	2.76	101	4.46
104	2.17	58	1.65	6.87	2.84	101	4.73
105	2.21	59	1.48	6.70	2.86	101	4.57
Mean	2.338	59.7	1.504	6.626	2.842	101.0	4.411
SD	0.144	2.5	0.360	0.739	0.061	0.7	0.224
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
121	2.63	57	0.74	6.61	2.65	103	3.75
122	2.54	56	0.39	7.29	2.58	103	4.12
123	2.61	59	0.91	4.75	2.67	103	3.68
124	2.76	59	0.80	8.39	2.74	103	3.75
125	2.72	55	0.22	8.56	2.54	104	4.08
131	2.60	57	0.53	7.51	2.77	102	3.59
132	2.56	61	0.50	8.93	2.78	103	3.95
133	2.64	53	0.32	6.51	2.56	103	4.12
134	2.57	57	0.38	7.68	2.65	103	4.22
135	2.46	56	0.28	9.63	2.45	103	3.99
Mean	2.609	57.0	0.507	7.586	2.639	103.0	3.925
SD	0.087	2.3	0.236	1.408	0.107	0.5	0.217
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
151	2.76	57	0.87	5.80	2.64	102	4.40
152	2.69	55	0.80	6.67	2.62	103	4.35
153	2.51	57	0.43	6.57	2.57	102	3.98
154	3.10	56	0.58	6.13	2.65	104	4.49
155	2.62	58	0.44	6.04	2.54	103	4.29
161	2.64	55	0.83	5.43	2.65	102	4.10
162	2.38	55	0.35	7.41	2.48	104	4.10
163	2.43	56	0.52	7.60	2.38	104	4.35
164	2.50	57	0.37	7.82	2.47	103	4.83
165	2.59	55	0.46	7.13	2.67	102	4.26
Mean	2.622	56.1	0.565	6.660	2.567	102.9	4.315
SD	0.204	1.1	0.197	0.812	0.097	0.9	0.239
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
181	2.74	57	0.51	7.50	2.44	103	4.09
182	2.09	59	0.35	7.64	2.69	103	4.56
183	2.30	58	0.52	6.12	2.87	100	4.02
184	2.77	53	0.34	6.80	2.57	103	3.54
185	2.66	56	0.36	5.24	2.66	104	4.35
191	2.45	53	0.41	5.55	2.54	103	3.96
192	2.60	53	0.57	6.11	2.55	104	4.11
193	2.60	55	0.54	7.61	2.52	104	3.75
194	2.72	59	0.88	11.36	2.65	103	3.97
195	2.76	56	0.59	9.05	2.83	103	4.08
Mean	2.569	55.9	0.507	7.298	2.632	103.0	4.043
SD	0.225	2.4	0.162	1.831	0.137	1.2	0.283
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
151	2.49	56	0.59	8.13	2.57	98	4.03
152	2.51	58	0.35	7.04	2.71	102	3.79
153	2.73	58	0.29	7.24	2.63	100	3.89
154	2.90	55	0.56	7.83	2.52	99	3.90
155	2.55	56	0.46	7.65	2.48	99	4.25
156	2.69	58	0.46	8.37	2.71	98	3.64
157	2.60	55	0.46	9.01	2.52	97	4.12
158	2.41	54	0.30	8.13	2.47	99	4.01
159	2.47	52	0.47	8.08	2.56	98	3.85
160	2.36	52	0.62	8.58	2.58	100	4.39
Mean	2.571	55.4	0.456	8.006	2.575	99.0	3.987
SD	0.163	2.3	0.115	0.595	0.086	1.4	0.223
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
1	1.99	55	0.26	7.30	2.57	101	4.51
2	1.81	53	0.26	7.79	2.45	104	4.04
3	1.90	57	0.46	7.48	2.57	101	3.91
4	2.60	54	0.63	6.14	2.71	101	4.38
5	2.68	55	0.60	6.68	2.59	100	3.29
6	2.42	54	0.49	6.27	2.48	99	3.55
7	2.28	55	0.42	8.16	2.64	101	3.88
8	2.21	50	0.45	7.36	2.43	100	3.52
9	2.45	50	0.30	5.96	2.54	100	4.20
10	2.11	54	0.26	6.54	2.48	99	3.76
Mean	2.245	53.7	0.413	6.968	2.546	100.6	3.904
SD	0.295	2.2	0.139	0.751	0.088	1.4	0.390
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
31	2.80	55	0.43	7.86	2.60	100	4.13
32	3.16	56	0.46	7.46	2.66	102	5.19
33	2.81	56	0.64	8.47	2.83	102	4.27
34	2.03	54	0.52	7.81	2.69	102	4.17
35	2.22	53	0.69	7.96	2.57	99	4.34
36	2.50	57	0.38	8.77	2.59	99	3.86
37	2.80	55	0.28	7.67	2.64	102	4.07
38	2.87	52	0.34	8.18	2.57	100	3.85
39	2.66	55	0.56	10.70	2.52	101	3.99
40	2.73	53	0.79	8.98	2.54	97	3.95
Mean	2.658	54.6	0.509	8.386	2.621	100.4	4.182
SD	0.329	1.6	0.163	0.947	0.090	1.7	0.390
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
61	2.72	54	0.56	7.19	2.48	99	3.94
62	2.58	56	0.65	8.31	2.47	99	3.81
63	2.48	51	0.44	8.25	2.40	99	3.84
64	1.99	56	0.61	7.94	2.59	102	4.13
65	2.15	54	0.52	8.34	2.48	98	3.89
66	2.42	55	0.46	8.27	2.45	99	3.83
67	2.39	50	0.56	8.03	2.56	100	4.14
68	2.38	55	0.59	6.88	2.59	100	3.87
69	2.59	54	0.57	8.37	2.62	101	4.02
70	2.46	52	0.44	11.09	2.48	101	4.12
Mean	2.416	53.7	0.540	8.267	2.512	99.8	3.959
SD	0.213	2.1	0.073	1.117	0.073	1.2	0.132
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
91	1.85	55	0.58	6.80	2.52	103	4.57
92	1.72	54	0.26	7.31	2.40	102	3.80
93	2.20	56	0.27	5.27	2.45	101	3.78
94	2.27	61	0.37	6.84	2.62	101	3.59
95	2.24	56	0.35	7.81	2.50	101	3.92
96	2.03	57	0.32	9.85	2.56	101	4.59
97	1.97	58	0.35	5.16	2.56	99	4.25
98	2.60	59	0.32	9.22	2.56	97	3.42
99	2.44	58	0.45	7.13	2.74	101	5.10
100	2.13	59	0.41	9.18	2.65	100	4.39
Mean	2.145	57.3	0.368	7.457	2.556	100.6	4.141
SD	0.265	2.1	0.094	1.596	0.098	1.6	0.527
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
121	2.77	59	0.54	9.33	2.52	99	3.43
122	2.61	57	0.32	6.61	2.56	101	4.11
123	2.31	58	0.71	7.32	2.53	99	4.05
124	2.45	60	0.53	8.56	2.65	103	4.76
125	2.34	56	0.41	10.04	2.47	99	3.96
126	2.38	59	0.60	10.19	2.59	103	4.36
127	1.95	59	0.51	8.71	2.65	100	4.19
128	1.87	60	0.46	8.18	2.64	100	4.19
129	2.24	63	0.48	8.22	2.65	100	3.61
130	4.16 E!	62	0.89	8.20	2.53	100	12.67 E!
Mean	2.324	59.3	0.545	8.536	2.579	100.4	4.073
SD	0.286	2.1	0.160	1.115	0.066	1.5	0.391
N	9	10	10	10	10	10	9

E = Exclude; ! = Result Comment

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
181	2.67	57	0.48	8.88	2.54	100	4.12
182	2.76	57	0.48	12.30	2.61	101	3.73
183	2.18	61	0.72	10.96	2.76	100	4.32
184	2.49	57	0.40	8.77	2.52	100	3.99
185	2.32	57	0.55	9.42	2.58	99	4.14
186	2.19	60	0.29	9.48	2.67	100	4.38
187	2.24	58	0.40	8.64	2.60	101	4.10
188	2.00	59	0.44	8.88	2.58	101	5.04
189	2.57	57	0.40	8.33	2.61	99	4.09
190	2.23	56	0.62	8.71	2.60	100	4.29
Mean	2.365	57.9	0.478	9.437	2.607	100.1	4.220
SD	0.245	1.6	0.124	1.246	0.068	0.7	0.342
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
161	1.90	57	0.45	6.41	2.50	104	3.65
162	1.87	55	0.45	6.86	2.33	103	3.89
163	1.87	54	0.75	5.91	2.34	104	3.80
164	3.14	57	0.30	6.88	2.50	105	5.93
165	1.82	56	0.38	6.47	2.40	103	3.94
Mean	2.120	55.8	0.466	6.506	2.414	103.8	4.242
SD	0.571	1.3	0.170	0.397	0.083	0.8	0.950
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
11	2.17	57	0.49	8.14	2.67	104	4.07
12	2.32	55	0.46	5.27	2.42	103	3.62
13	1.98	57	0.61	8.06	2.60	104	4.17
14	1.99	57	0.52	5.70	2.60	103	4.00
15	2.23	55	0.41	6.68	2.44	102	3.75
Mean	2.138	56.2	0.498	6.770	2.546	103.2	3.922
SD	0.150	1.1	0.075	1.318	0.110	0.8	0.229
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
41	2.36	58	0.41	6.65	2.60	103	3.96
42	2.10	55	0.28	6.91	2.57	101	4.08
43	2.00	54	0.44	6.92	2.43	102	4.19
44	2.50	56	0.72	8.14	2.62	101	4.07
45	2.00	54	0.53	7.29	2.48	103	4.04
Mean	2.192	55.4	0.476	7.182	2.540	102.0	4.068
SD	0.227	1.7	0.163	0.582	0.082	1.0	0.083
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
71	2.52	54	0.29	7.88	2.48	102	3.72
72	2.17	53	0.42	6.20	2.55	102	3.33
73	2.13	53	0.32	7.15	2.40	102	4.10
74	2.02	52	0.42	7.91	2.51	103	4.21
75	1.74	55	0.69	8.59	2.47	105	4.36
Mean	2.116	53.4	0.428	7.546	2.482	102.8	3.944
SD	0.281	1.1	0.158	0.909	0.055	1.3	0.417
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
101	2.03	56	0.55	9.19	2.45	103	3.98
102	1.92	59	0.62	6.76	2.40	104	3.84
103	2.34	57	0.51	7.67	2.42	102	3.95
104	2.30	60	0.66	6.60	2.58	102	3.61
105	1.91	53	0.50	7.96	2.47	105	4.08
Mean	2.100	57.0	0.568	7.636	2.464	103.2	3.892
SD	0.207	2.7	0.070	1.044	0.070	1.3	0.179
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
131	2.05	56	0.68	7.55	2.56	103	4.29
132	1.96	52	0.81	6.73	2.54	104	3.94
133	2.65	51	0.42	9.15	2.46	102	3.98
134	2.18	57	0.39	6.25	2.54	102	4.05
135	1.96	51	0.39	8.77	2.41	104	4.05
Mean	2.160	53.4	0.538	7.690	2.502	103.0	4.062
SD	0.288	2.9	0.195	1.256	0.064	1.0	0.136
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
191	2.26	59	0.60	7.63	2.59	103	4.22
192	2.31	57	0.89	7.71	2.55	104	4.09
193	2.01	57	0.59	9.47	2.53	105	4.16
194	2.16	56	0.55	7.29	2.47	105	3.82
195	2.23	55	0.93	5.37	2.47	103	3.92
Mean	2.194	56.8	0.712	7.494	2.522	104.0	4.042
SD	0.116	1.5	0.182	1.460	0.052	1.0	0.167
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
1	136	65	249	70	98	134	1.0
2	136	65	249	86	78	158	1.5
3	135	61	277	76	56	94	2.4
4	134	56	391	76	106	125	2.4
5	135	111	222	115	111	173	0.3
11	135	57	294	67	66	115	0.1
12	135	73	249	82	112	152	0.1 !
13	136	59	208	78	87	97	0.4
14	136	59	246	79	98	115	0.6
15	134	55	317	74	88	109	0.7
Mean	135.2	66.1	270.2	80.3	90.0	127.2	0.95
SD	0.8	16.7	53.3	13.4	18.9	26.6	0.87
N	10	10	10	10	10	10	10

! = Result Comment

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
31	136	55	222	87	54	150	4.0
32	136	55	227	84	47	95	4.5
33	136	68	239	81	90	126	4.5
34	136	69	292	88	82	207	4.9
35	135	64	246	93	78	170	5.6
41	135	51	255	84	58	198	4.5
42	134	54	273	83	57	137	5.1
43	134	56	329	80	102	210	3.0
44	135	52	260	83	51	123	2.6
45	137	45	236	88	67	351	3.4
Mean	135.4	56.9	257.9	85.1	68.6	176.7	4.21
SD	1.0	7.7	32.8	3.9	18.5	72.5	0.96
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
61	136	48	131	90	113	113	2.9
62	138	42	161	94	112	273	2.6
63	137	41	128	93	96	20	3.3
64	136	47	247	97	111	215	2.6
65	136	51	181	112	170	47	1.8
71	137	57	283	106	143	106	3.6
72	136	62	204	110	133	229	3.2
73	136	39	150	107	120	33	3.3
74	136	50	180	97	87	20	2.9
75	138	51	153	89	90	144	3.1
Mean	136.6	48.8	181.8	99.5	117.5	120.0	2.93
SD	0.8	7.1	50.3	8.5	25.6	93.1	0.51
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
91	136	51	278	72	58	113	3.0
92	136	63	320	82	77	156	1.4
93	136	52	252	78	75	291	3.0
94	136	68	227	70	71	123	2.3
95	135	69	239	76	149	261	2.5
101	137	68	277	84	68	217	3.1
102	136	73	240	79	97	194	2.7
103	135	58	277	72	62	85	2.0
104	136	49	206	72	77	268	2.9
105	136	68	259	88	81	458	2.3
Mean	135.9	61.9	257.5	77.3	81.5	216.6	2.52
SD	0.6	8.7	32.2	6.0	26.0	110.3	0.54
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
121	138	57	214	86	122	108	3.9
122	137	35	153	67	74	95	4.4
123	138	44	173	86	80	26	2.9
124	138	61	203	94	100	127	2.4
125	137	41	241	94	192	10	3.5
131	136	44	180	87	128	224	2.4
132	137	48	213	95	152	347	3.9
133	137	39	221	82	88	106	3.2
134	137	39	180	80	135	145	3.3
135	138	48	172	99	194	139	3.3
Mean	137.3	45.6	195.0	87.0	126.5	132.7	3.32
SD	0.7	8.2	27.4	9.3	43.1	96.4	0.65
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
151	136	38	145	87	153	52	2.8
152	136	53	172	100	111	139	5.2
153	136	42	208	94	111	137	4.0
154	137	47	218	104	153	227	4.2
155	138	43	167	89	124	152	4.5
161	138	43	171	91	110	127	4.3
162	137	47	197	93	80	221	2.7
163	138	42	206	96	133	158	1.4
164	136	44	214	92	184	154	3.5
165	136	43	200	108	190	160	3.4
Mean	136.8	44.2	189.8	95.4	134.9	152.7	3.60
SD	0.9	4.0	24.3	6.7	35.0	48.9	1.09
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
181	136	47	172	82	172	161	2.3
182	138	45	213	93	85	83	1.3
183	136	67	225	96	80	14	2.9
184	138	44	211	99	156	151	2.8
185	138	31	163	93	172	198	2.9
191	138	37	224	103	168	151	4.5
192	137	45	248	112	185	247	3.0
193	138	45	225	102	97	192	3.6
194	137	39	188	83	128	174	4.9
195	137	44	230	96	144	180	4.3
Mean	137.3	44.4	209.9	95.9	138.7	155.1	3.25
SD	0.8	9.3	27.2	9.0	39.1	64.8	1.09
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
151	132	43	132	97	141	147	3.3
152	133	49	165	116	125	141	6.1
153	133	45	164	108	140	221	3.1
154	131	58	177	125	163	233	2.8
155	132	46	152	108	133	167	3.1
156	134	55	178	100	108	111	4.0
157	129	49	148	101	131	128	4.2
158	131	51	160	113	112	208	5.6
159	133	47	169	110	67	92	3.2
160	133	52	158	126	126	78	4.4
Mean	132.1	49.5	160.3	110.4	124.6	152.6	3.98
SD	1.4	4.6	13.9	9.9	25.5	53.9	1.12
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
1	134	39	149	82	172	98	1.5
2	136	40	158	84	130	341	0.7
3	135	31	155	60	49	116	2.5
4	136	32	223	84	102	372	2.0
5	135	50	140	110	70	104	2.9
6	133	38	135	70	44	127	0.5
7	135	30	135	74	113	89	1.0
8	135	27	151	67	87	70	1.9
9	134	26	157	68	132	129	1.6
10	134	46	169	100	196	134	1.6
Mean	134.7	35.9	157.2	79.9	109.5	158.0	1.62
SD	0.9	8.0	25.5	15.6	49.9	106.7	0.76
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
31	134	44	201	113	95	154	4.2
32	135	29	166	91	196	193	3.8
33	136	54	169	116	147	311	4.4
34	136	41	232	106	119	120	3.2
35	133	34	157	97	175	118	5.6
36	132	44	181	95	117	165	4.7
37	136	32	204	82	65	120	4.4
38	132	48	155	115	143	168	4.5
39	134	31	232	85	121	159	5.4
40	130	44	209	113	162	148	4.1
Mean	133.8	40.1	190.6	101.3	134.0	165.6	4.43
SD	2.0	8.2	29.1	12.9	38.8	56.6	0.70
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
61	132	52	124	114	167	168	2.6
62	133	37	114	73	55	142	3.8
63	132	45	121	114	141	124	2.5
64	135	40	191	104	172	120	3.1
65	132	38	128	100	154	139	1.5
66	133	32	103	76	102	106	3.7
67	134	38	139	102	121	95	2.1
68	132	37	133	64	45	94	3.7
69	134	42	173	98	134	122	4.5
70	134	28	105	93	150	137	2.9
Mean	133.1	38.9	133.1	93.8	124.1	124.7	3.04
SD	1.1	6.6	28.5	17.3	44.2	22.9	0.90
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
91	133	36	153	98	133	111	4.1
92	136	37	177	101	92	126	4.2
93	133	38	134	89	80	229	2.9
94	135	34	127	77	58	136	3.1
95	136	29	133	78	81	192	3.7
96	134	37	142	93	146	179	4.5
97	133	40	123	89	102	178	3.0
98	132	36	114	88	82	137	3.8
99	137	40	123	94	128	139	3.5
100	135	35	178	80	132	115	3.1
Mean	134.4	36.2	140.4	88.7	103.4	154.2	3.59
SD	1.6	3.2	22.3	8.2	29.5	38.4	0.56
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
121	132	37	159	96	141	158	4.0
122	133	27	156	78	106	123	5.4
123	132	31	132	70	102	102	4.0
124	136	39	162	84	146	118	3.3
125	132	36	217	87	77	187	4.2
126	134	43	201	99	115	143	6.0
127	133	31	161	82	155	120	4.0
128	133	34	154	88	115	130	4.9
129	133	27	150	85	119	134	3.2
130	126	74	151	308 E!	2274 E!	245	2.8
Mean	132.4	37.9	164.3	85.4	119.6	146.0	4.18
SD	2.5	13.7	25.3	8.7	24.4	42.1	1.00
N	10	10	10	9	9	10	10

E = Exclude; ! = Result Comment

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
181	132	28	127	73	126	128	4.9
182	133	35	170	94	86	162	4.9
183	133	32	152	77	109	101	5.4
184	132	34	176	106	133	129	5.4
185	133	28	144	83	126	121	4.7
186	132	39	201	91	117	125	4.4
187	133	26	182	85	133	115	4.1
188	133	37	194	96	164	126	3.6
189	133	35	229	93	116	141	4.4
190	133	46	246	93	133	116	6.5
Mean	132.7	34.0	182.1	89.1	124.3	126.4	4.83
SD	0.5	6.0	37.1	9.7	20.1	16.3	0.81
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
161	138	49	117	110	122	226	2.3
162	138	48	119	84	138	115	2.0
163	139	42	144	85	99	78	2.2
164	140	47	143	72	150	197	1.5
165	137	34	126	80	93	101	1.2
Mean	138.4	44.0	129.8	86.2	120.4	143.4	1.84
SD	1.1	6.2	12.9	14.3	24.5	64.4	0.47
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
11	137	35	134	71	107	76	2.8
12	137	38	100	116	215	1117	1.6
13	135	32	100	69	106	114	3.6
14	137	31	94	76	78	133	1.7
15	137	37	126	70	61	85	3.3
Mean	136.6	34.6	110.8	80.4	113.4	305.0	2.60
SD	0.9	3.0	17.9	20.1	60.0	454.5	0.91
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
41	137	36	120	77	72	98	2.5
42	136	29	106	75	57	201	3.2
43	134	39	124	80	69	180	2.7
44	135	36	120	84	141	506	3.5
45	136	37	119	75	144	119	1.8
Mean	135.6	35.4	117.8	78.2	96.6	220.8	2.74
SD	1.1	3.8	6.9	3.8	42.3	165.0	0.66
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
71	138	37	145	86	140	82	1.8
72	138	42	116	83	52	67	2.0
73	137	36	84	109	209	354	1.9
74	138	33	90	75	101	92	2.6
75	140	37	103	80	161	273	1.1
Mean	138.2	37.0	107.6	86.6	132.6	173.6	1.88
SD	1.1	3.2	24.3	13.2	59.6	131.2	0.54
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766574

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
101	137	40	156	95	151	103	2.3
102	140	45	115	92	50	84	1.6
103	135	39	138	81	51	92	2.2
104	137	37	94	87	68	267	2.4
105	140	41	162	83	42	82	3.0
Mean	137.8	40.4	133.0	87.6	72.4	125.6	2.30
SD	2.2	3.0	28.5	5.9	44.9	79.5	0.50
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
131	138	44	143	102	179	282	0.6
132	139	40	112	87	68	338	0.3
133	137	35	157	74	52	199	1.9
134	136	37	114	76	127	252	1.6
135	139	44	106	105	102	107	2.3
Mean	137.8	40.0	126.4	88.8	105.6	235.6	1.34
SD	1.3	4.1	22.3	14.3	50.4	87.7	0.86
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
191	137	46	108	79	71	285	0.5
192	138	46	155	102	69	99	3.2
193	139	41	100	79	75	67	1.6
194	139	33	120	77	77	434	1.8
195	139	33	104	76	79	114	2.0
Mean	138.4	39.8	117.4	82.6	74.2	199.8	1.82
SD	0.9	6.5	22.3	10.9	4.1	155.9	0.97
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
16	29.6	24.4	1.21	3.5	1.76	42	11.14
17	29.7	28.3	1.05	4.7	1.53	42	7.86
18	32.3	28.7	1.13	4.6	1.67	45	8.72
19	31.0	27.0	1.15	3.3	2.20	44	9.52
20	32.3	25.7	1.26	3.2	2.07	44	8.60
26	33.7	28.3	1.19	4.1	2.26	43	8.87
27	31.5	28.5	1.11	2.4	1.47	38	9.94
28	30.3	26.7	1.13	3.1	1.64	46	8.47
29	32.2	29.8	1.08	3.5	2.28	45	8.39
30	33.5	29.5	1.14	2.7	1.77	45	8.86
Mean	31.61	27.69	1.144	3.51	1.865	43.4	9.037
SD	1.45	1.71	0.062	0.76	0.309	2.3	0.940
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
46	27.6	28.4	0.97	3.7	2.15	44	7.90
47	27.6	31.4	0.88	3.1	2.40	40	9.43
48	26.4	28.6	0.92	4.4	2.15	41	8.33
49	26.4	27.6	0.96	3.1	1.64	41	8.78
50	28.6	29.4	0.97	3.5	1.97	44	8.16
56	26.5	28.5	0.93	3.5	1.36	40	8.70
57	28.0	30.0	0.93	5.2	1.96	43	9.78
58	27.4	28.6	0.96	3.3	2.64	45	10.20
59	28.0	29.0	0.97	3.7	1.56	43	8.73
60	25.0	28.0	0.89	3.3	2.06	40	9.34
Mean	27.15	28.95	0.938	3.68	1.989	42.1	8.935
SD	1.06	1.09	0.033	0.65	0.388	1.9	0.737
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
76	28.3	26.7	1.06	2.9	2.10	50	6.29
77	26.9	23.1	1.16	2.3	1.86	45	9.88
78	27.7	28.3	0.98	3.4	2.70	39	5.46
79	27.0	23.0	1.17	2.8	1.73	45	6.75
80	30.1	27.9	1.08	2.6	2.12	45	6.18
86	27.4	25.6	1.07	2.4	1.77	45	6.56
87	27.5	24.5	1.12	2.4	2.14	40	5.73
88	28.0	26.0	1.08	2.8	2.16	43	8.70
89	29.3	26.7	1.10	3.1	2.10	47	6.69
90	28.1	24.9	1.13	3.2	1.94	45	6.65
Mean	28.03	25.67	1.095	2.79	2.062	44.4	6.889
SD	1.01	1.82	0.057	0.37	0.275	3.2	1.362
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
106	27.4	28.6	0.96	2.6	1.82	44	9.82
107	29.9	29.1	1.03	2.5	2.01	43	9.44
108	28.6	32.4	0.88	2.6	1.75	42	7.82
109	29.6	30.4	0.97	2.7	2.25	43	8.63
110	29.5	33.5	0.88	3.6	1.96	41	7.57
116	28.1	28.9	0.97	2.2	1.92	44	9.52
117	27.8	31.2	0.89	2.4	2.39	42	9.36
118	29.6	29.4	1.01	2.6	1.76	42	8.89
119	30.0	29.0	1.03	2.2	1.90	43	8.73
120	29.2	30.8	0.95	2.3	1.55	42	8.63
Mean	28.97	30.33	0.958	2.57	1.931	42.6	8.841
SD	0.93	1.65	0.057	0.40	0.245	1.0	0.731
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
136	28.7	29.3	0.98	2.3	2.38	42	9.69
137	27.7	27.3	1.01	2.3	1.51	44	9.99
138	27.3	26.7	1.02	2.7	1.68	47	6.58
139	29.1	29.9	0.97	3.2	1.27	48	7.08
140	28.4	34.6	0.82	3.2	1.99	43	6.23
146	27.2	28.8	0.94	3.2	1.40	42	9.05
147	29.1	32.9	0.88	2.9	2.70	41	6.09
148	28.2	28.8	0.98	2.7	2.06	36	4.97
149	27.8	27.2	1.02	2.3	1.86	43	6.67
150	28.6	33.4	0.86	2.9	1.80	45	6.32
Mean	28.21	29.89	0.950	2.77	1.865	43.1	7.267
SD	0.69	2.80	0.072	0.37	0.441	3.3	1.698
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
166	27.7	26.3	1.05	3.3	2.14	47	6.65
167	28.2	27.8	1.01	2.8	1.83	45	7.05
168	28.8	28.2	1.02	3.0	1.86	41	5.92
169	26.9	26.1	1.03	2.9	1.87	42	8.28
170	28.2	26.8	1.05	3.3	1.97	47	5.50
176	28.7	29.3	0.98	3.2	2.13	45	9.08
177	27.7	26.3	1.05	3.4	1.52	44	9.52
178	27.4	30.6	0.90	2.3	2.40	43	9.36
179	28.5	28.5	1.00	3.4	2.39	42	5.72
180	27.1	22.9	1.18	3.1	1.37	46	6.54
Mean	27.92	27.28	1.028	3.07	1.948	44.2	7.362
SD	0.66	2.12	0.072	0.34	0.336	2.1	1.562
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
196	28.0	29.0	0.97	3.4	1.58	48	6.35
197	27.2	28.8	0.94	2.5	2.03	42	5.10
198	26.5	27.5	0.96	2.4	1.79	42	6.21
199	27.5	27.5	1.00	3.3	2.14	40	8.81
200	27.4	27.6	0.99	2.4	1.63	41	5.94
206	28.2	28.8	0.98	2.7	1.84	46	5.70
207	27.9	28.1	0.99	2.5	1.75	40	7.25
208	29.4	32.6	0.90	2.4	2.23	45	7.47
209	28.2	29.8	0.95	2.6	1.65	40	6.05
210	25.9	27.1	0.96	3.1	1.89	44	6.33
Mean	27.62	28.68	0.964	2.73	1.853	42.8	6.521
SD	0.97	1.62	0.029	0.39	0.220	2.8	1.059
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
166	27.6	26.4	1.05	3.0	2.06	47	8.21
167	28.5	28.5	1.00	2.9	1.76	43	7.73
168	27.8	26.2	1.06	3.3	1.66	42	7.70
169	27.3	26.7	1.02	2.8	1.75	49	9.08
170	27.5	24.5	1.12	3.1	1.36	45	7.07
171	26.3	23.7	1.11	2.9	1.16	49	7.81
172	27.6	28.4	0.97	3.4	1.69	49	8.27
173	27.5	27.5	1.00	3.1	1.49	42	7.90
174	26.8	24.2	1.11	3.0	1.68	51	8.83
175	26.6	25.4	1.05	2.8	1.71	48	7.84
Mean	27.35	26.15	1.049	3.03	1.632	46.5	8.044
SD	0.64	1.70	0.052	0.20	0.246	3.3	0.582
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
16	29.7	23.3	1.27	2.2	1.66	52	9.51
17	29.3	28.7	1.02	2.6	1.15	46	8.50
18	31.5	26.5	1.19	3.1	1.56	42	10.23
19	28.4	24.6	1.15	3.4	2.40	47	8.43
20	31.6	26.4	1.20	3.6	2.01	51	9.21
21	30.9	26.1	1.18	3.1	1.90	46	10.47
22	29.7	24.3	1.22	2.7	1.42	41	9.56
23	30.9	25.1	1.23	4.0	2.18	48	9.70
24	31.7	26.3	1.21	2.9	1.95	49	8.62
25	29.9	24.1	1.24	2.7	1.41	46	10.79
Mean	30.36	25.54	1.192	3.03	1.764	46.8	9.502
SD	1.12	1.57	0.069	0.53	0.389	3.5	0.829
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
46	26.9	28.1	0.96	3.4	2.03	48	9.10
47	27.7	28.3	0.98	3.5	2.03	53	7.86
48	27.1	30.9	0.88	3.5	2.11	50	8.70
49	26.3	24.7	1.06	4.3	1.44	48	6.03
50	28.6	29.4	0.97	4.0	1.83	48	7.59
51	28.5	36.5	0.78	3.9	2.35	46	8.31
52	27.0	26.0	1.04	4.4	1.13	43	6.89
53	28.9	30.1	0.96	5.0	1.68	49	7.84
54	27.9	29.1	0.96	4.7	1.80	47	7.77
55	27.9	27.1	1.03	3.7	1.78	47	8.11
Mean	27.68	29.02	0.962	4.04	1.818	47.9	7.820
SD	0.84	3.23	0.083	0.55	0.349	2.6	0.873
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
76	27.4	27.6	0.99	2.8	2.38	48	10.88
77	27.7	26.3	1.05	3.5	2.23	46	8.83
78	26.9	26.1	1.03	3.5	2.41	49	7.62
79	27.4	25.6	1.07	3.5	1.91	48	8.65
80	26.9	25.1	1.07	3.6	1.79	46	8.04
81	28.0	23.0	1.22	3.3	1.27	52	7.92
82	29.2	24.8	1.18	4.0	1.53	52	7.40
83	28.4	26.6	1.07	3.9	1.77	50	7.70
84	27.8	28.2	0.99	3.3	2.10	48	8.58
85	27.2	24.8	1.10	4.7	1.55	53	9.71
Mean	27.69	25.81	1.076	3.61	1.894	49.2	8.533
SD	0.71	1.50	0.073	0.51	0.384	2.5	1.076
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
106	26.0	28.0	0.93	3.4	1.60	47	11.67
107	27.5	27.5	1.00	2.9	1.48	49	6.88
108	28.2	31.8	0.89	4.5	1.21	43	8.25
109	27.0	29.0	0.93	2.5	1.89	49	7.68
110	29.7	33.3	0.89	2.8	1.60	46	8.48
111	27.4	30.6	0.90	3.2	1.70	48	9.29
112	26.7	30.3	0.88	2.6	1.16	47	9.94
113	26.4	29.6	0.89	2.8	1.64	48	8.72
114	27.1	30.9	0.88	2.9	1.09	48	6.19
115	27.8	30.2	0.92	3.0	1.11	47	9.04
Mean	27.38	30.12	0.910	3.06	1.448	47.2	8.614
SD	1.04	1.72	0.037	0.57	0.284	1.8	1.551
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
136	26.4	28.6	0.92	3.8	1.53	48	8.12
137	27.9	30.1	0.93	3.9	1.73	47	7.51
138	25.9	24.1	1.07	2.9	1.32	49	9.96
139	28.0	30.0	0.93	4.0	1.01	49	7.43
140	27.2	29.8	0.91	5.0	1.28	49	7.78
141	29.5	33.5	0.88	4.5	2.07	54	8.03
142	26.6	29.4	0.90	3.4	1.54	47	9.39
143	26.9	28.1	0.96	3.6	1.65	48	6.65
144	26.9	30.1	0.89	2.7	1.15	54	9.29
145	26.4	28.6	0.92	4.5	1.16	48	7.51
Mean	27.17	29.23	0.933	3.83	1.444	49.3	8.167
SD	1.05	2.34	0.054	0.72	0.322	2.6	1.046
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
196	27.1	28.9	0.94	5.1	1.25	50	7.78
197	26.4	28.6	0.92	5.5	1.53	46	9.07
198	27.6	32.4	0.85	2.5	1.17	53	11.01
199	26.9	30.1	0.89	3.1	1.25	46	9.37
200	28.2	29.8	0.95	3.8	1.45	51	7.30
201	27.3	28.7	0.95	3.4	1.14	53	8.94
202	27.1	31.9	0.85	5.1	1.25	51	7.70
203	26.9	29.1	0.92	3.7	1.52	47	9.22
204	25.6	28.4	0.90	3.5	1.09	55	7.24
205	27.2	32.8	0.83	3.9	1.40	50	7.24
Mean	27.03	30.07	0.901	3.96	1.305	50.2	8.487
SD	0.69	1.68	0.044	0.97	0.159	3.1	1.241
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
176	31.2	28.8	1.08	3.7	1.57	58	10.02
177	29.9	28.1	1.06	3.5	1.07	54	8.85
178	33.7	30.3	1.11	4.0	2.39	48	10.44
179	30.2	28.8	1.05	2.5	1.80	49	9.89
180	30.5	26.5	1.15	3.6	1.37	55	8.33
Mean	31.10	28.50	1.092	3.46	1.640	52.8	9.506
SD	1.53	1.38	0.041	0.57	0.498	4.2	0.880
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Choleste-rol (total) (mmol/L)	Crea-tinine (µmol/L)	Glucose (mmol/L)
26	32.9	29.1	1.13	3.1	2.42	53	11.08
27	30.1	29.9	1.01	2.7	1.34	54	9.10
28	28.0	29.0	0.97	2.8	1.52	53	9.60
29	31.7	30.3	1.05	2.6	2.21	56	7.47
30	33.6	29.4	1.14	2.7	1.90	60	8.43
Mean	31.26	29.54	1.058	2.78	1.878	55.2	9.136
SD	2.25	0.55	0.077	0.19	0.453	2.9	1.348
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
56	30.1	28.9	1.04	2.8	1.30	51	9.36
57	34.2	31.8	1.08	5.2	2.14	51	8.79
58	29.7	29.3	1.01	2.6	2.87	52	10.33
59	31.1	32.9	0.95	2.8	1.39	59	6.61
60	29.7	30.3	0.98	3.5	2.06	49	9.02
Mean	30.96	30.64	1.011	3.38	1.952	52.4	8.822
SD	1.90	1.69	0.051	1.07	0.638	3.8	1.369
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
86	29.9	25.1	1.19	3.6	1.32	54	8.70
87	29.2	24.8	1.18	3.4	1.59	50	7.81
88	29.8	22.2	1.34	3.0	2.00	50	9.94
89	29.3	22.7	1.29	2.9	1.27	51	10.15
90	30.6	24.4	1.25	3.4	1.95	50	11.49
Mean	29.76	23.84	1.251	3.26	1.626	51.0	9.618
SD	0.56	1.30	0.069	0.30	0.342	1.7	1.414
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
116	30.3	31.7	0.96	2.5	1.78	60	9.80
117	30.3	28.7	1.06	2.9	1.80	54	10.38
118	32.1	30.9	1.04	3.4	1.58	52	11.70
119	30.3	27.7	1.09	2.8	1.92	51	7.72
120	31.0	31.0	1.00	3.4	1.82	57	10.97
Mean	30.80	30.00	1.029	3.00	1.780	54.8	10.114
SD	0.79	1.71	0.053	0.39	0.124	3.7	1.512
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
146	28.5	24.5	1.16	2.6	1.24	53	11.75
147	33.0	31.0	1.06	3.5	2.73	50	10.91
148	32.2	26.8	1.20	2.6	2.05	52	6.75
149	29.1	25.9	1.12	3.2	1.47	65	9.53
150	31.6	30.4	1.04	3.8	1.53	56	11.88
Mean	30.88	27.72	1.118	3.14	1.804	55.2	10.164
SD	1.97	2.85	0.067	0.54	0.596	5.9	2.126
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Albumin (g/L)	Globulin (g/L)	Alb./Glob. Ratio	Bilirubin (total) (µmol/L)	Cholesterol (total) (mmol/L)	Creatinine (µmol/L)	Glucose (mmol/L)
206	31.2	28.8	1.08	2.8	2.05	47	8.13
207	30.2	27.8	1.09	3.3	1.96	55	12.40
208	31.4	23.6	1.33	3.0	2.50	52	9.87
209	30.7	27.3	1.12	2.8	2.08	50	6.96
210	29.0	28.0	1.04	2.4	1.60	52	9.31
Mean	30.50	27.10	1.132	2.86	2.038	51.2	9.334
SD	0.96	2.03	0.115	0.33	0.321	2.9	2.048
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
16	1.87	54	2.06	6.45	2.64	102	4.19
17	2.58	58	1.54	7.49	2.81	101	4.45
18	2.09	61	2.22	9.09	2.74	102	4.42
19	2.37	58	1.30	7.13	2.81	103	4.22
20	2.09	58	1.11	6.26	2.79	103	3.78
26	2.19	62	2.36	7.19	2.88	102	4.48
27	1.99	60	0.87	5.60	2.69	102	3.88
28	2.41	57	1.26	6.40	2.79	101	4.23
29	2.41	62	2.17	7.01	2.90	101	4.58
30	2.07	63	0.71	6.51	2.65	105	4.21
Mean	2.207	59.3	1.560	6.913	2.770	102.2	4.244
SD	0.225	2.8	0.602	0.943	0.089	1.2	0.257
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
46	2.52	56	2.19	7.54	2.83	101	4.10
47	2.23	59	1.22	7.27	2.93	103	4.38
48	2.28	55	2.41	6.98	2.90	100	4.36
49	2.54	54	1.54	6.16	2.78	101	3.84
50	2.56	58	1.62	7.03	2.80	100	3.90
56	2.53	55	1.90	6.41	2.71	100	4.05
57	2.46	58	2.89	6.53	2.84	100	4.22
58	2.38	56	1.49	5.70	2.77	102	3.93
59	2.47	57	1.22	7.98	2.81	100	4.14
60	2.90	53	1.98	8.06	2.78	100	4.26
Mean	2.487	56.1	1.846	6.966	2.815	100.7	4.118
SD	0.183	1.9	0.538	0.775	0.064	1.1	0.190
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
76	2.52	55	0.74	7.66	2.66	103	3.69
77	2.15	50	0.38	7.60	2.55	104	4.11
78	2.75	56	0.52	7.15	2.82	102	4.04
79	2.02	50	0.54	5.67	2.60	103	3.45
80	2.21	58	0.62	5.22	2.76	103	3.86
86	2.20	53	0.46	7.19	2.53	103	3.83
87	2.44	52	0.44	4.95	2.72	103	3.81
88	2.00	54	0.44	8.01	2.49	103	3.78
89	2.27	56	0.61	4.83	2.63	104	4.17
90	2.22	53	0.46	7.94	2.64	105	3.70
Mean	2.278	53.7	0.521	6.622	2.640	103.3	3.844
SD	0.231	2.6	0.109	1.299	0.104	0.8	0.216
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
106	2.18	56	1.33	5.99	2.80	101	4.68
107	2.37	59	0.83	5.61	2.86	100	3.74
108	2.40	61	0.68	7.85	2.81	102	4.68
109	2.27	60	1.21	7.35	2.86	103	4.22
110	2.19	63	1.32	7.08	2.89	102	4.05
116	2.46	57	0.67	6.21	2.64	103	4.20
117	2.28	59	0.67	6.93	2.77	102	4.15
118	2.46	59	1.26	8.03	2.94	101	4.37
119	2.24	59	0.50	7.42	2.76	102	3.85
120	2.44	60	0.59	7.17	2.85	101	4.32
Mean	2.329	59.3	0.906	6.964	2.818	101.7	4.226
SD	0.110	1.9	0.334	0.795	0.083	0.9	0.309
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
136	2.35	58	0.39	6.44	2.84	104	4.19
137	2.11	55	0.42	6.04	2.70	102	4.48
138	2.07	54	0.28	7.70	2.50	104	3.69
139	2.60	59	0.27	8.61	2.69	104	4.25
140	2.28	63	0.84	6.48	2.77	104	3.76
146	1.96	56	0.80	6.72	2.81	102	4.78
147	2.50	62	0.70	7.00	2.79	103	3.82
148	2.69	57	0.71	6.64	2.80	103	4.04
149	2.26	55	0.48	4.75	2.55	103	3.62
150	2.39	62	0.45	5.66	2.79	104	3.77
Mean	2.321	58.1	0.534	6.604	2.724	103.3	4.040
SD	0.234	3.3	0.211	1.059	0.115	0.8	0.381
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
166	2.49	54	0.66	8.02	2.61	103	4.00
167	2.71	56	0.57	6.86	2.67	104	4.02
168	2.38	57	0.32	4.38	2.66	104	3.68
169	2.74	53	0.53	6.20	2.70	102	4.07
170	2.81	55	0.62	7.51	2.70	102	3.95
176	2.23	58	0.77	6.16	2.71	102	4.02
177	2.11	54	0.82	6.74	2.72	102	4.37
178	2.63	58	1.26	6.72	2.89	101	4.31
179	2.52	57	0.54	7.71	2.81	102	3.78
180	2.74	50	0.69	9.05	2.62	103	3.86
Mean	2.536	55.2	0.678	6.935	2.709	102.5	4.006
SD	0.236	2.5	0.248	1.262	0.085	1.0	0.214
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
196	2.11	57	0.32	6.03	2.56	105	3.66
197	2.60	56	0.31	5.87	2.70	104	3.99
198	2.39	54	0.52	5.81	2.73	103	4.04
199	2.41	55	0.93	6.16	2.72	102	4.64
200	2.25	55	0.37	6.36	2.60	104	3.70
206	2.28	57	0.37	7.42	2.73	104	4.14
207	2.16	56	0.34	5.60	2.66	103	3.81
208	2.29	62	0.38	6.14	2.81	103	4.32
209	2.47	58	0.35	5.34	2.74	104	3.71
210	2.59	53	0.52	6.74	2.69	101	3.79
Mean	2.355	56.3	0.441	6.147	2.694	103.3	3.980
SD	0.167	2.5	0.187	0.594	0.072	1.2	0.316
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
166	1.90	54	0.51	9.09	2.54	102	4.04
167	2.17	57	0.43	7.95	2.64	101	4.19
168	2.17	54	0.47	7.89	2.75	99	4.45
169	2.11	54	0.56	8.00	2.46	102	3.64
170	2.28	52	0.33	8.73	2.68	101	4.07
171	2.36	50	0.35	7.77	2.53	100	3.99
172	2.34	56	0.54	9.82	2.53	96	4.12
173	2.25	55	0.63	8.56	2.64	100	3.81
174	2.53	51	0.37	9.29	2.56	100	3.55
175	2.25	52	0.34	8.82	2.64	101	4.33
Mean	2.236	53.5	0.453	8.592	2.597	100.2	4.019
SD	0.167	2.2	0.105	0.687	0.087	1.8	0.285
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
16	1.98	53	0.37	7.92	2.44	101	3.05
17	1.54	58	0.23	7.41	2.55	102	3.98
18	1.99	58	0.34	7.06	2.61	103	3.60
19	2.45	53	0.58	6.35	2.80	100	3.52
20	1.95	58	0.28	10.15	2.67	102	3.09
21	1.70	57	0.34	8.10	2.50	101	3.71
22	1.44	54	0.34	6.57	2.42	103	3.34
23	2.07	56	0.35	6.34	2.62	103	3.90
24	1.66	58	0.27	9.22	2.56	102	3.83
25	1.67	54	0.30	9.51	2.57	102	3.88
Mean	1.845	55.9	0.340	7.863	2.574	101.9	3.590
SD	0.300	2.2	0.095	1.373	0.111	1.0	0.336
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
46	2.28	55	0.78	7.97	2.67	101	3.89
47	2.16	56	0.51	7.52	2.66	100	4.00
48	2.28	58	0.42	6.84	2.66	102	3.77
49	2.37	51	0.60	7.30	2.53	99	3.55
50	2.07	58	0.42	7.97	2.62	98	3.48
51	2.09	65	0.51	6.67	2.81	101	4.18
52	2.39	53	0.31	6.51	2.66	102	3.87
53	2.58	59	0.39	10.55	2.73	101	3.86
54	2.48	57	0.36	7.42	2.81	100	4.30
55	1.76	55	0.45	9.75	2.51	104	4.09
Mean	2.246	56.7	0.475	7.850	2.666	100.8	3.899
SD	0.237	3.8	0.136	1.322	0.100	1.7	0.259
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
76	1.84	55	0.53	8.00	2.70	102	4.15
77	1.70	54	0.60	9.30	2.49	105	3.81
78	2.04	53	0.41	8.73	2.45	101	3.89
79	2.03	53	0.41	8.09	2.55	103	4.11
80	2.13	52	0.88	7.99	2.67	102	4.07
81	2.47	51	0.35	9.13	2.57	102	3.85
82	1.92	54	0.93	6.43	2.54	102	3.71
83	2.13	55	0.64	7.33	2.72	102	4.04
84	2.30	56	0.89	9.55	2.71	101	4.36
85	1.87	52	0.39	6.39	2.47	103	3.97
Mean	2.043	53.5	0.603	8.094	2.587	102.3	3.996
SD	0.228	1.6	0.225	1.122	0.104	1.2	0.190
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
106	2.29	54	0.30	7.18	2.56	102	4.34
107	2.01	55	0.42	6.79	2.64	101	3.77
108	2.17	60	0.32	8.29	2.80	100	4.21
109	2.66	56	0.48	7.54	2.74	102	3.84
110	1.84	63	0.35	8.12	2.76	102	3.67
111	2.27	58	0.33	8.58	2.72	101	3.99
112	1.90	57	0.27	9.67	2.59	102	4.11
113	2.12	56	0.44	7.98	2.71	100	3.74
114	2.26	58	0.37	9.06	2.49	102	3.64
115	1.72	58	0.29	7.84	2.62	101	3.71
Mean	2.124	57.5	0.357	8.105	2.663	101.3	3.902
SD	0.272	2.6	0.070	0.857	0.099	0.8	0.246
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
136	2.16	55	0.47	7.74	2.74	100	4.06
137	2.36	58	0.59	8.28	2.62	102	4.37
138	1.50	50	0.37	9.92	2.48	103	4.08
139	1.64	58	0.27	8.64	2.65	102	4.17
140	2.54	57	0.54	9.61	2.68	99	4.42
141	2.02	63	0.37	8.04	2.74	102	3.93
142	1.98	56	0.46	6.22	2.64	102	4.32
143	2.56	55	0.53	7.73	2.55	100	3.37
144	1.97	57	0.33	10.60	2.59	101	4.83
145	2.15	55	0.51	7.75	2.71	103	4.25
Mean	2.088	56.4	0.444	8.453	2.640	101.4	4.180
SD	0.347	3.3	0.104	1.284	0.084	1.3	0.378
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
196	2.17	56	0.51	8.72	2.71	103	4.10
197	2.27	55	0.41	8.10	2.71	101	4.37
198	1.86	60	0.47	9.84	2.83	104	4.38
199	1.94	57	0.26	7.38	2.61	101	3.46
200	1.82	58	0.29	6.71	2.63	103	3.39
201	2.30	56	0.54	9.53	2.74	101	3.92
202	2.19	59	0.39	8.16	2.75	102	4.27
203	2.12	56	0.57	7.77	2.64	101	4.00
204	2.01	54	0.52	9.98	2.65	104	3.80
205	1.71	60	0.54	7.05	2.58	104	3.85
Mean	2.039	57.1	0.450	8.324	2.685	102.4	3.954
SD	0.202	2.1	0.109	1.162	0.076	1.3	0.346
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
176	1.50	60	0.28	7.13	2.49	103	3.56
177	1.79	58	0.24	5.88	2.45	102	3.66
178	1.56	64	0.61	8.93	2.66	101	3.32
179	1.63	59	0.43	8.11	2.46	102	3.54
180	2.02	57	0.42	6.94	2.55	103	3.57
Mean	1.700	59.6	0.396	7.398	2.522	102.2	3.530
SD	0.209	2.7	0.146	1.166	0.086	0.8	0.126
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
26	1.33	62	0.55	9.27	2.57	101	3.64
27	1.78	60	0.34	7.40	2.59	105	3.04
28	1.81	57	0.36	7.54	2.46	102	3.98
29	1.58	62	0.30	7.99	2.66	103	3.36
30	1.65	63	0.49	7.85	2.64	105	3.50
Mean	1.630	60.8	0.408	8.010	2.584	103.2	3.504
SD	0.192	2.4	0.107	0.743	0.078	1.8	0.347
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
56	1.61	59	0.38	6.95	2.50	104	3.50
57	1.98	66	0.47	6.57	2.66	104	3.22
58	1.71	59	0.42	8.90	2.55	101	3.83
59	1.91	64	0.33	6.51	2.49	105	2.97
60	1.72	60	0.43	9.48	2.53	104	3.61
Mean	1.786	61.6	0.406	7.682	2.546	103.6	3.426
SD	0.153	3.2	0.053	1.402	0.068	1.5	0.336
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
86	2.10	55	0.37	9.10	2.43	102	3.83
87	1.85	54	0.32	8.49	2.44	103	3.79
88	1.76	52	0.49	8.54	2.48	101	3.86
89	1.56	52	0.44	7.58	2.46	102	3.56
90	1.88	55	0.47	8.12	2.57	104	3.71
Mean	1.830	53.6	0.418	8.366	2.476	102.4	3.750
SD	0.196	1.5	0.071	0.562	0.056	1.1	0.120
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
116	1.80	62	0.26	9.22	2.47	103	3.37
117	1.68	59	0.37	7.35	2.62	103	3.58
118	1.78	63	0.36	8.55	2.68	104	3.99
119	1.86	58	0.45	7.47	2.52	104	3.21
120	1.78	62	0.30	9.36	2.64	102	3.72
Mean	1.780	60.8	0.348	8.390	2.586	103.2	3.574
SD	0.065	2.2	0.073	0.946	0.088	0.8	0.304
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
146	1.57	53	0.25	7.69	2.47	102	3.82
147	1.33	64	0.79	6.26	2.56	104	3.51
148	1.58	59	0.38	5.98	2.47	102	2.99
149	2.27	55	0.42	7.81	2.30	103	3.59
150	2.13	62	0.58	8.41	2.65	102	3.70
Mean	1.776	58.6	0.484	7.230	2.490	102.6	3.522
SD	0.403	4.6	0.208	1.054	0.130	0.9	0.319
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Phosphate (mmol/L)	Protein (total) (g/L)	Tri-glycerides (mmol/L)	Urea (in blood) (mmol/L)	Calcium (mmol/L)	Chloride (mmol/L)	Potassium (mmol/L)
206	2.32	60	0.51	8.18	2.69	104	3.97
207	1.69	58	0.45	6.53	2.48	101	3.67
208	1.41	55	0.34	8.17	2.53	105	3.95
209	2.36	58	0.36	7.01	2.45	103	3.30
210	1.76	57	0.32	7.75	2.40	103	3.01
Mean	1.908	57.6	0.396	7.528	2.510	103.2	3.580
SD	0.416	1.8	0.081	0.733	0.111	1.5	0.418
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766619

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
16	136	59	138	86	76	207	0.1 !
17	135	61	172	83	99	129	0.8
18	136	61	148	85	122	88	1.9
19	135	51	136	51	66	51	1.5
20	137	59	132	71	87	164	0.8
26	135	50	149	65	82	136	1.2
27	136	46	169	41	59	85	0.2
28	135	65	214	75	99	94	0.7
29	135	70	139	79	73	129	0.3
30	138	51	145	109	98	97	1.3
Mean	135.8	57.3	154.2	74.5	86.1	118.0	0.88
SD	1.0	7.6	24.9	19.2	18.8	44.8	0.59
N	10	10	10	10	10	10	10

! = Result Comment

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
46	135	61	231	91	83	158	4.6
47	138	54	168	98	74	124	3.2
48	135	64	251	84	67	341	4.7
49	135	59	219	85	72	96	3.5
50	135	54	159	80	54	92	2.6
56	134	50	217	84	65	80	5.4
57	135	54	138	77	60	96	3.4
58	135	55	184	71	72	63	1.6
59	134	75	190	108	83	131	4.2
60	134	65	223	80	57	155	3.5
Mean	135.0	59.1	198.0	85.8	68.7	133.6	3.67
SD	1.2	7.4	35.9	10.7	10.0	79.3	1.10
N	10	10	10	10	10	10	10

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
76	136	55	192	107	99	19	3.3
77	137	37	129	109	122	236	2.6
78	136	57	152	93	73	139	3.4
79	136	49	142	93	105	86	2.7
80	137	39	145	106	142	243	2.8
86	136	44	124	107	109	360	2.4
87	139	41	143	85	63	88	3.1
88	136	41	120	84	97	106	3.2
89	138	31	135	96	231	241	2.4
90	137	61	135	108	162	16	1.6
Mean	136.8	45.5	141.7	98.8	120.3	153.4	2.75
SD	1.0	9.7	20.2	9.8	48.7	112.3	0.54
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766622

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
106	135	47	182	75	52	144	2.4
107	135	55	133	77	70	104	2.6
108	135	59	187	77	53	71	2.0
109	137	44	155	71	71	97	0.7
110	136	39	165	66	82	95	2.4
116	136	34	151	75	97	277	2.2
117	135	57	185	94	68	239	1.7
118	135	75	208	87	68	121	2.6
119	136	48	159	84	57	69	1.9
120	134	32	152	52	58	80	4.7
Mean	135.4	49.0	167.7	75.8	67.6	129.7	2.32
SD	0.8	13.0	22.3	11.6	13.9	71.8	1.01
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766623

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
136	138	49	138	97	88	120	4.1
137	135	41	140	98	114	13	1.3
138	138	30	132	96	201	163	2.3
139	136	40	130	95	195	9	4.0
140	137	40	214	89	98	127	5.8
146	136	51	140	87	161	487	3.7
147	136	33	141	72	79	26	3.5
148	138	49	175	108	113	29	4.9
149	136	37	154	87	105	99	2.1
150	137	31	142	78	96	117	5.5
Mean	136.7	40.1	150.6	90.7	125.0	119.0	3.72
SD	1.1	7.6	25.7	10.4	44.3	140.6	1.48
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766624

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
166	136	42	124	85	140	32	4.2
167	136	55	173	109	91	24	2.4
168	138	45	143	106	146	116	4.7
169	135	42	185	101	141	23	4.3
170	135	47	110	109	143	392	3.2
176	136	71	180	120	156	99	4.1
177	136	54	158	117	236	206	3.1
178	135	64	164	113	102	315	3.0
179	135	53	156	101	143	134	4.6
180	135	48	122	111	131	26	4.1
Mean	135.7	52.1	151.5	107.2	142.9	136.7	3.77
SD	0.9	9.5	25.9	9.9	38.5	130.2	0.78
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766625

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
196	138	23	154	78	138	140	3.6
197	137	32	166	103	138	157	4.5
198	137	38	118	89	131	140	3.2
199	135	44	182	90	139	48	4.5
200	138	42	125	90	78	87	4.3
206	136	34	160	109	104	136	3.7
207	139	29	155	78	67	98	3.4
208	135	42	186	110	236	6	5.9
209	138	32	177	100	118	233	3.0
210	135	48	190	119	184	16	4.0
Mean	136.8	36.4	161.3	96.6	133.3	106.1	4.01
SD	1.5	7.7	24.5	13.8	49.2	69.8	0.85
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766626

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
166	135	129	109	160	80	82	3.7
167	133	63	168	124	119	113	4.5
168	130	58	145	119	121	101	4.6
169	134	35	165	113	124	145	5.2
170	133	46	118	118	124	129	4.9
171	132	48	122	111	96	137	4.2
172	128	35	104	100	120	158	5.4
173	132	65	143	123	77	105	3.5
174	133	62	134	127	118	140	3.0
175	133	40	209	130	107	112	3.6
Mean	132.3	58.1	141.7	122.5	108.6	122.2	4.26
SD	2.0	27.4	32.1	15.8	18.1	23.4	0.79
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766627

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
16	135	31	72	83	46	64	0.6
17	135	31	92	83	181	133	0.9
18	135	30	71	72	110	98	0.3
19	134	26	72	60	106	158	1.2
20	134	42	73	96	179	154	1.8
21	134	36	64	85	148	98	1.4
22	135	49	73	87	146	87	1.2
23	136	27	60	70	103	97	1.1
24	136	36	86	90	103	92	2.4
25	135	34	96	80	131	85	1.2
Mean	134.9	34.2	75.9	80.6	125.3	106.6	1.21
SD	0.7	7.0	11.7	10.6	40.6	31.1	0.59
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766628

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
46	134	31	154	89	106	104	5.0
47	132	120	113	156	152	216	3.0
48	134	47	177	109	102	127	4.3
49	132	43	138	109	168	183	3.9
50	131	44	142	95	126	112	4.7
51	133	67	163	122	190	135	3.8
52	134	37	178	109	124	113	3.4
53	134	55	184	124	129	109	4.7
54	133	81	174	152	220	536	4.0
55	134	53	136	122	100	122	2.9
Mean	133.1	57.8	155.9	118.7	141.7	175.7	3.97
SD	1.1	26.2	23.2	21.8	40.2	131.6	0.72
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766629

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
76	136	41	170	115	116	352	4.5
77	137	30	112	80	185	82	5.4
78	133	40	93	90	165	127	3.6
79	136	43	137	114	176	102	1.1
80	134	38	144	99	141	133	3.4
81	133	36	121	79	119	99	3.4
82	133	34	82	98	171	448	2.0
83	133	50	119	102	181	110	2.0
84	132	35	123	88	130	252	3.2
85	134	32	104	88	175	118	4.6
Mean	134.1	37.9	120.5	95.3	155.9	182.3	3.32
SD	1.7	5.9	25.5	12.6	26.7	125.9	1.33
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766630

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
106	133	36	114	103	143	347	2.3
107	134	42	77	102	119	115	3.0
108	133	44	142	99	133	78	4.5
109	135	27	86	74	140	363	4.0
110	131	26	110	63	46	67	2.9
111	134	33	128	88	127	204	6.0
112	135	31	149	91	123	100	4.2
113	134	40	93	84	56	121	3.2
114	133	28	89	76	49	97	4.4
115	132	36	99	84	110	158	4.9
Mean	133.4	34.3	108.7	86.4	104.6	165.0	3.94
SD	1.3	6.4	24.5	13.0	38.7	107.7	1.10
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766631

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
136	128	45	135	115	167	136	3.7
137	133	38	151	115	187	411	4.3
138	135	39	191	103	163	157	5.1
139	132	27	136	100	168	131	4.1
140	131	40	206	118	149	242	5.0
141	134	32	121	99	181	106	3.7
142	133	32	129	99	146	235	4.9
143	133	30	170	91	50	109	5.2
144	132	25	159	92	112	170	4.3
145	135	26	191	95	151	140	3.7
Mean	132.6	33.4	158.9	102.7	147.4	183.7	4.40
SD	2.1	6.8	29.6	9.9	40.1	92.6	0.61
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766632

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
196	134	26	204	101	174	166	5.6
197	133	45	198	134	266	114	4.5
198	136	35	144	91	200	142	5.0
199	132	32	195	96	131	149	5.0
200	135	29	168	91	90	171	3.0
201	131	19	205	94	85	110	4.9
202	132	33	161	104	202	189	5.2
203	133	32	223	98	122	116	5.3
204	137	29	172	97	197	151	5.6
205	135	28	168	96	87	88	6.4
Mean	133.8	30.8	183.8	100.2	155.4	139.6	5.05
SD	1.9	6.7	24.6	12.5	61.5	31.8	0.88
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0766633

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
176	138	26	74	77	138	88	2.4
177	136	29	72	100	110	703	1.8
178	135	49	72	123	106	184	1.8
179	136	32	80	71	126	154	2.5
180	137	24	44	62	110	124	2.2
Mean	136.4	32.0	68.4	86.6	118.0	250.6	2.14
SD	1.1	10.0	14.0	24.7	13.6	255.4	0.33
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766634

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
26	135	35	54	82	62	93	3.0
27	140	28	63	74	53	84	1.2
28	134	29	83	72	135	171	2.8
29	137	41	59	77	56	168	2.4
30	138	44	48	91	41	85	3.0
Mean	136.8	35.4	61.4	79.2	69.4	120.2	2.48
SD	2.4	7.1	13.3	7.6	37.5	45.2	0.76
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766635

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
56	138	29	57	82	54	60	3.4
57	137	76	37	172	203	671	1.9
58	134	29	80	51	30	48	3.3
59	139	35	73	91	40	141	3.3
60	139	34	90	78	123	105	3.4
Mean	137.4	40.6	67.4	94.8	90.0	205.0	3.06
SD	2.1	20.0	20.8	45.7	72.9	263.1	0.65
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0766636

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
86	135	35	85	83	141	151	2.1
87	136	29	72	81	176	166	2.8
88	135	32	71	61	74	85	0.5
89	137	28	69	73	122	206	1.4
90	137	38	65	99	150	969	1.9
Mean	136.0	32.4	72.4	79.4	132.6	315.4	1.74
SD	1.0	4.2	7.5	14.0	38.1	368.0	0.86
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
116	137	24	64	72	59	168	3.2
117	136	41	64	105	83	136	2.6
118	137	32	63	91	158	349	1.4
119	137	32	63	88	46	111	2.6
120	136	23	69	67	155	278	2.8
Mean	136.6	30.4	64.6	84.6	100.2	208.4	2.52
SD	0.5	7.3	2.5	15.3	53.1	101.2	0.67
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
146	137	38	67	72	108	194	2.2
147	137	30	56	61	53	51	1.6
148	137	34	62	87	50	79	3.2
149	136	37	88	114	193	324	1.8
150	138	38	51	93	138	179	1.8
Mean	137.0	35.4	64.8	85.4	108.4	165.4	2.12
SD	0.7	3.4	14.3	20.3	60.2	108.1	0.64
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Biochemical Parameters						
	Sodium (mmol/L)	ALAT (U/L)	aP (U/L)	ASAT (U/L)	LDH (U/L)	CK (U/L)	Gamma-GT (U/L)
206	138	36	73	71	43	123	2.4
207	135	36	69	75	87	120	2.5
208	138	34	59	98	172	253	1.8
209	139	24	68	80	80	156	2.0
210	139	28	66	87	63	107	3.5
Mean	137.8	31.6	67.0	82.2	89.0	151.8	2.44
SD	1.6	5.4	5.1	10.7	49.4	59.4	0.66
N	5	5	5	5	5	5	5

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	5	Male	130	Phosphate	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			
	17	5	Male	130	Potassium	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	4	1	Male	12	Gamma-GT	Result	
			Comment:	Value below lowest level of quantification (= 0.1 U/L). Set to 0.1 U/L for mean value calculation.			
	17	5	Male	130	ASAT	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			
	17	5	Male	130	Lactate Dehy drogenase	Quality Flag	E (Exclude)
			Comment:	animal died during blood sampling, sampling was done via heart puncture during dissection			

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TABLE 7-2 Biochemical Parameters - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	4	1	Female	16	Gamma-GT	Result	

Comment: Value below lowest level of quantification (= 0.1 U/L). Set to 0.1 U/L for mean value calculation.

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a1]
Group 1: Control	Mean	64658.6	39774.6
	SD	6727.8	3460.7
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	465027.0**	727036.0**
	SD	68141.1	243939.8
	N	5	5
	%Diff	619.2	1727.9
Group 3: 10 µg/ animal BNT162a1	Mean	304707.0**	222958.2
	SD	34632.5	118385.8
	N	5	5
	%Diff	371.3	460.6
Group 4: 30 µg/ animal BNT162b1	Mean	381868.0**	1434571.0**
	SD	30666.8	522399.7
	N	5	5
	%Diff	490.6	3506.8

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	454853.0**	2143050.0**
	SD	23446.8	71797.8
	N	5	5
	%Diff	603.5	5288.0
Group 6: 30 µg/ animal BNT162c1	Mean	431128.0**	685548.0**
	SD	60320.6	364534.3
	N	5	5
	%Diff	566.8	1623.6
Group 7: 100 µg/ animal BNT162b2	Mean	446781.0**	2159010.0**
	SD	64502.0	78652.0
	N	5	5
	%Diff	591.0	5328.1

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	416278.0 n	545282.5 n
	SD	34413.2	368839.8
	N	10	10
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 1: Control	Mean	50334.7	21233.0
	SD	11962.9	2975.2
	N	10	10
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	429643.0**	551658.5**
	SD	17527.1	201887.8
	N	10	10
	%Diff	753.6	2498.1
Group 3: 10 µg/ animal BNT162a1	Mean	737003.5**	394276.5**
	SD	124583.7	207037.7
	N	10	10
	%Diff	1364.2	1756.9
Group 4: 30 µg/ animal BNT162b1	Mean	437627.0**	930437.0**
	SD	54732.7	608722.2
	N	10	10
	%Diff	769.4	4282.0

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	970915.5**	5927330.0**
	SD	72264.9	2354973.1
	N	10	10
	%Diff	1828.9	27815.7
Group 7: 100 µg/ animal BNT162b2	Mean	1043631.5**	4604490.0**
	SD	80157.0	1488181.0
	N	10	10
	%Diff	1973.4	21585.5

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	120039.4 n	24501.2 n
	SD	26150.6	8533.2
	N	5	5
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a1]
Group 1: Control	Mean	113897.4	14847.8
	SD	28082.4	4958.1
	N	5	5
	-		
Group 2: 30 µg/ animal BNT162a1	Mean	96757.2	19435.4
	SD	22123.3	4049.4
	N	5	5
	%Diff	-15.0	30.9
Group 3: 10 µg/ animal BNT162a1	Mean	58193.4 **	16261.0
	SD	6901.6	5138.0
	N	5	5
	%Diff	-48.9	9.5
Group 4: 30 µg/ animal BNT162b1	Mean	106850.8	20052.6
	SD	19090.7	4943.1
	N	5	5
	%Diff	-6.2	35.1

[a] - Anova & Dunnett(Log): ** = p ≤ 0.01
[a1] - Anova & Dunnett

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	65259.8**	22707.2*
	SD	5082.1	2406.8
	N	5	5
	%Diff	-42.7	52.9
Group 7: 100 µg/ animal BNT162b2	Mean	59438.6**	24303.8*
	SD	5558.8	4950.4
	N	5	5
	%Diff	-47.8	63.7

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a1]
Group 1: Control	Mean	79798.8	18098.2
	SD	17269.9	5486.8
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	401386.0**	126189.4**
	SD	32156.3	63343.9
	N	5	5
	%Diff	403.0	597.2
Group 3: 10 µg/ animal BNT162a1	Mean	323645.0**	57146.0**
	SD	46893.3	15460.1
	N	5	5
	%Diff	305.6	215.8
Group 4: 30 µg/ animal BNT162b1	Mean	378897.0**	330428.0**
	SD	29869.1	292586.3
	N	5	5
	%Diff	374.8	1725.8

[a] - Anova & Dunnett: ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log): ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 4 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	444957.0**	1639367.0**
	SD	21643.8	557054.1
	N	5	5
	%Diff	457.6	8958.2
Group 6: 30 µg/ animal BNT162c1	Mean	390580.0**	169592.0**
	SD	23209.4	138784.7
	N	5	5
	%Diff	389.5	837.1
Group 7: 100 µg/ animal BNT162b2	Mean	445614.0**	1362630.0**
	SD	27975.1	257962.6
	N	5	5
	%Diff	458.4	7429.1

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	409704.5 n	134878.1 n
	SD	31388.8	77962.6
	N	10	10
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 1: Control	Mean	52001.7	16055.9
	SD	10058.1	3899.1
	N	10	10
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	467670.5**	269274.2**
	SD	35882.2	133874.6
	N	10	10
	%Diff	799.3	1577.1
Group 3: 10 µg/ animal BNT162a1	Mean	649429.5**	102489.3**
	SD	236844.1	45691.2
	N	10	10
	%Diff	1148.9	538.3
Group 4: 30 µg/ animal BNT162b1	Mean	463014.0**	723981.3**
	SD	31240.3	560182.5
	N	10	10
	%Diff	790.4	4409.1

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	980874.0**	2692160.0**
	SD	86180.9	1082703.5
	N	10	10
	%Diff	1786.2	16667.4
Group 7: 100 µg/ animal BNT162b2	Mean	826053.0**	1937467.5**
	SD	274115.3	1018132.7
	N	10	10
	%Diff	1488.5	11967.0

[a] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	110891.8 n	14755.0 n
	SD	46262.6	4860.1
	N	5	5
		-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 1: Control	Mean	131519.8	22175.8
	SD	46366.1	12640.6
	N	5	5
	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	110365.6	20030.0
	SD	66482.3	7218.8
	N	5	5
	%Diff	-16.1	-9.7
Group 3: 10 µg/ animal BNT162a1	Mean	75601.0	17691.0
	SD	12035.1	3218.6
	N	5	5
	%Diff	-42.5	-20.2
Group 4: 30 µg/ animal BNT162b1	Mean	153412.0	18945.4
	SD	35789.9	5115.2
	N	5	5
	%Diff	16.6	-14.6

[a] - Anova & Dunnett(Log)

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		ELISA Parameters	
		Alpha1-acid Glycoprotein (ng/mL) [a]	Alpha2 Macroglob. (ng/mL) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	61578.2*	15699.0
	SD	15860.4	2853.3
	N	5	5
	%Diff	-53.2	-29.2
Group 7: 100 µg/ animal BNT162b2	Mean	90184.8	18626.8
	SD	37898.0	4975.0
	N	5	5
	%Diff	-31.4	-16.0

[a] - Anova & Dunnett: * = $p \leq 0.05$

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	2	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	3	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	4	5	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Male	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	38	3	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	38	5	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	38	5	Male	Alpha2 Macroglob.	*	Anova & Dunnett: * = p ≤ 0.05
	38	7	Male	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	7	Male	Alpha2 Macroglob.	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 8-1 Acute Phase Protein Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	4	2	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	2	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	3	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	3	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	4	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	4	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	4	5	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	5	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	6	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	4	7	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	10	6	Female	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	17	2	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	Alpha2 Macroglob.	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Alpha1-acid Glycoprotein	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Alpha2 Macroglob.	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Female	Alpha1-acid Glycoprotein	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Alpha2 Macroglob.	n	Anova & Dunnett: n - Inappropriate for statistics
	38	5	Female	Alpha1-acid Glycoprotein	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
6	74598	35466
7	58677	40751
8	61115	41545
9	60338	44022
10	68565	37089
Mean	64658.6	39774.6
SD	6727.8	3460.7
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
36	395770	484880
37	412245	585995
38	445750	690305
39	553485	749950
40	517885	1124050
Mean	465027.0	727036.0
SD	68141.1	243939.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
66	346280	377430
67	270970	203495
68	337625	301160
69	281405	77781
70	287255	154925
Mean	304707.0	222958.2
SD	34632.5	118385.8
N	5	5

FDA-CBER-2021-5683-0766665

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
96	370705	1912550
97	379860	864255
98	430975	1283450
99	346930	2048950
100	380870	1063650
Mean	381868.0	1434571.0
SD	30666.8	522399.7
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
126	431675	2115250
127	447855	2072450
128	436225	2230700
129	485375	2208100
130	473135	2088750
Mean	454853.0	2143050.0
SD	23446.8	71797.8
N	5	5

FDA-CBER-2021-5683-0766667

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
156	449640	1171250
157	517280	220825
158	440650	541515
159	383510	586840
160	364560	907310
Mean	431128.0	685548.0
SD	60320.6	364534.3
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
186	553550	2173650
187	446970	2280300
188	380375	2071850
189	424225	2111900
190	428785	2157350
Mean	446781.0	2159010.0
SD	64502.0	78652.0
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
151	387715	838040
152	472405	313110
153	457165	1109700
154	416455	102745
155	361605	349125
156	409100	1085600
157	440805	189125
158	382780	234195
159	406110	558865
160	428640	672320
Mean	416278.0	545282.5
SD	34413.2	368839.8
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
1	52385	18903
2	48381	18818
3	38406	18703
4	57563	20376
5	79663	19897
6	51049	23285
7	42368	26508
8	43867	25944
9	39404	18960
10	50261	20936
Mean	50334.7	21233.0
SD	11962.9	2975.2
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
31	416505	229715
32	445745	679065
33	423550	662375
34	455465	351035
35	420835	271255
36	449005	529270
37	397930	649710
38	425580	657965
39	422215	845810
40	439600	640385
Mean	429643.0	551658.5
SD	17527.1	201887.8
N	10	10

FDA-CBER-2021-5683-0766672

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
61	569265	420140
62	830325	513405
63	614150	176050
64	766735	796895
65	698405	123535
66	760240	586800
67	738910	210390
68	1015700	430440
69	653585	270590
70	722720	414520
Mean	737003.5	394276.5
SD	124583.7	207037.7
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
91	427380	891365
92	338995	237575
93	428700	1304000
94	446240	591510
95	442385	515650
96	550585	1503900
97	465035	627240
98	459370	717540
99	434330	2295800
100	383250	619790
Mean	437627.0	930437.0
SD	54732.7	608722.2
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
121	967885	3106700
122	999355	9085700
123	1035755	3212850
124	1106600	4229650
125	855035	4742600
126	986870	5079750
127	896930	4686550
128	966370	8248600
129	906785	8282400
130	987570	8598500
Mean	970915.5	5927330.0
SD	72264.9	2354973.1
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
181	1028100	6341900
182	1138600	6339200
183	1085150	2191950
184	1157050	2305250
185	1057100	5455250
186	876725	5700650
187	968455	4722350
188	1039285	3928800
189	1054500	4971650
190	1031350	4087900
Mean	1043631.5	4604490.0
SD	80157.0	1488181.0
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
161	160530	18377
162	104896	28337
163	118340	36891
164	125305	23605
165	91126	15296
Mean	120039.4	24501.2
SD	26150.6	8533.2
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
11	111670	21367
12	105050	8140
13	74092	12503
14	129530	17146
15	149145	15083
Mean	113897.4	14847.8
SD	28082.4	4958.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
41	99122	24580
42	99224	17621
43	103371	22609
44	60729	17702
45	121340	14665
Mean	96757.2	19435.4
SD	22123.3	4049.4
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
71	67806	7398
72	58939	18308
73	60966	16405
74	50273	20133
75	52983	19061
Mean	58193.4	16261.0
SD	6901.6	5138.0
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
101	112525	15056
102	132825	19432
103	112570	21809
104	84998	27544
105	91336	16422
Mean	106850.8	20052.6
SD	19090.7	4943.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
131	67438	23757
132	73194	22919
133	62850	22600
134	61675	25397
135	61142	18863
Mean	65259.8	22707.2
SD	5082.1	2406.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
191	56500	28453
192	66800	23159
193	56846	18625
194	63641	30314
195	53406	20968
Mean	59438.6	24303.8
SD	5558.8	4950.4
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
21	72103	27364
22	109835	17256
23	66184	15792
24	73415	12823
25	77457	17256
Mean	79798.8	18098.2
SD	17269.9	5486.8
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
51	453710	127030
52	409260	58599
53	372545	215525
54	388245	155175
55	383170	74618
Mean	401386.0	126189.4
SD	32156.3	63343.9
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
81	260710	81274
82	314615	57579
83	388650	41085
84	342995	46586
85	311255	59206
Mean	323645.0	57146.0
SD	46893.3	15460.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
111	366335	292215
112	366000	115510
113	342730	261475
114	405375	836545
115	414045	146395
Mean	378897.0	330428.0
SD	29869.1	292586.3
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
141	420535	1819650
142	452305	1156100
143	428725	1986800
144	475845	2270400
145	447375	963885
Mean	444957.0	1639367.0
SD	21643.8	557054.1
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
171	388200	50410
172	425095	409540
173	386875	130920
174	359935	114400
175	392795	142690
Mean	390580.0	169592.0
SD	23209.4	138784.7
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 4 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
201	446180	1198200
202	448515	1787900
203	488465	1426900
204	432770	1225650
205	412140	1174500
Mean	445614.0	1362630.0
SD	27975.1	257962.6
N	5	5

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
166	423555	76401
167	454355	65135
168	417625	127105
169	367710	196325
170	381070	150105
171	358060	68208
172	411240	308885
173	427500	183410
174	414135	69107
175	441795	104100
Mean	409704.5	134878.1
SD	31388.8	77962.6
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
16	68688	11887
17	49113	20572
18	42397	19727
19	59898	16584
20	57776	16556
21	55998	22213
22	48929	13657
23	38037	14152
24	39498	9965
25	59683	15246
Mean	52001.7	16055.9
SD	10058.1	3899.1
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
46	516310	383415
47	440495	120600
48	457805	322615
49	432595	56572
50	456585	219120
51	531800	385690
52	463720	227270
53	472725	488200
54	487040	319150
55	417630	170110
Mean	467670.5	269274.2
SD	35882.2	133874.6
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
76	722315	95389
77	692045	114150
78	644855	169520
79	791675	46772
80	927205	142640
81	864770	40796
82	600415	57460
83	772365	97147
84	244590	161820
85	234060	99199
Mean	649429.5	102489.3
SD	236844.1	45691.2
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
106	466190	997090
107	419330	85513
108	533860	1565800
109	468610	599795
110	489860	980535
111	439375	385720
112	445075	115180
113	449440	577540
114	459390	1647550
115	459010	285090
Mean	463014.0	723981.3
SD	31240.3	560182.5
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
136	1072200	2451900
137	983855	3642700
138	823020	812900
139	909230	2210000
140	919480	2527250
141	958720	2256200
142	948335	2975500
143	1034250	3283350
144	1098450	4835050
145	1061200	1926750
Mean	980874.0	2692160.0
SD	86180.9	1082703.5
N	10	10

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
196	993680	1811950
197	1035050	879530
198	811530	2606800
199	1035220	4249000
200	920600	1368850
201	348300	2365000
202	298335	2156150
203	879555	1468150
204	946385	668495
205	991875	1800750
Mean	826053.0	1937467.5
SD	274115.3	1018132.7
N	10	10

FDA-CBER-2021-5683-0766697

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
176	159020	15840
177	92176	14190
178	162220	14064
179	70844	21641
180	70199	8040
Mean	110891.8	14755.0
SD	46262.6	4860.1
N	5	5

FDA-CBER-2021-5683-0766698

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
26	99854	12361
27	212740	16751
28	106205	17671
29	113690	19838
30	125110	44258
Mean	131519.8	22175.8
SD	46366.1	12640.6
N	5	5

FDA-CBER-2021-5683-0766699

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
56	215790	27646
57	81273	26344
58	125535	10664
59	90135	20242
60	39095	15254
Mean	110365.6	20030.0
SD	66482.3	7218.8
N	5	5

FDA-CBER-2021-5683-0766700

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
86	92486	15177
87	59378	19022
88	79867	21365
89	73747	19339
90	72527	13552
Mean	75601.0	17691.0
SD	12035.1	3218.6
N	5	5

FDA-CBER-2021-5683-0766701

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
116	207035	18509
117	108505	19144
118	146360	24941
119	162080	10972
120	143080	21161
Mean	153412.0	18945.4
SD	35789.9	5115.2
N	5	5

FDA-CBER-2021-5683-0766702

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
146	76975	17039
147	39454	17000
148	57978	13710
149	56413	11844
150	77071	18902
Mean	61578.2	15699.0
SD	15860.4	2853.3
N	5	5

FDA-CBER-2021-5683-0766703

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TABLE 8-2 Acute Phase Protein Levels - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	ELISA Parameters	
	Alpha1-acid Glycoprotein (ng/mL)	Alpha2 Macroglob. (ng/mL)
206	60346	26320
207	69090	20888
208	154730	15969
209	92067	14265
210	74691	15692
Mean	90184.8	18626.8
SD	37898.0	4975.0
N	5	5

FDA-CBER-2021-5683-0766704

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	7.23	7.10	12.60	3.00	9.90
	SD	5.60	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.00	15.50	29.20*	3.00 n	9.90 n
	SD	0.00	8.83	26.62	0.00	0.00
	N	3	3	3	3	3
	%Diff	-44.7	118.3	131.7	0.0	0.0
Group 3: 10 µg/ animal BNT162a1	Mean	10.23	7.10	12.60	3.00 n	9.90 n
	SD	10.80	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	41.5	0.0	0.0	0.0	0.0
Group 4: 30 µg/ animal BNT162b1	Mean	4.00	7.10	12.60	3.00 n	9.90 n
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-44.7	0.0	0.0	0.0	0.0

[a] - Anova & Dunnett(Rank): * = p ≤ 0.05; n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	4.27	7.10	12.60	3.00 n	9.90 n
100 µg/	SD	0.46	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-41.0	0.0	0.0	0.0	0.0
Group 6:	Mean	7.53	7.10	12.60	3.00 n	9.90 n
30 µg/	SD	6.12	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162c1	%Diff	4.1	0.0	0.0	0.0	0.0
Group 7:	Mean	5.57	7.37	12.60	3.00 n	9.90 n
100 µg/	SD	2.71	0.46	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b2	%Diff	-23.0	3.8	0.0	0.0	0.0

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	99.17	66.10	349.93	12.33	212.37
	SD	7.60	14.69	115.46	8.31	116.87
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	123.47	87.53	464.57	6.80	157.93
	SD	33.70	19.00	114.06	4.59	127.75
	N	3	3	3	3	3
	%Diff	24.5	32.4	32.8	-44.9	-25.6
Group 3: 10 µg/ animal BNT162a1	Mean	80.13	49.33	250.90	3.00*	147.77
	SD	16.85	11.69	64.36	0.00	24.44
	N	3	3	3	3	3
	%Diff	-19.2	-25.4	-28.3	-75.7	-30.4
Group 4: 30 µg/ animal BNT162b1	Mean	82.40	64.43	347.47	9.20	190.77
	SD	11.49	7.01	38.18	1.44	38.89
	N	3	3	3	3	3
	%Diff	-16.9	-2.5	-0.7	-25.4	-10.2

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): * = p ≤ 0.05

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	92.57	56.07	286.73	3.40	164.13
100 µg/	SD	12.93	15.61	80.42	0.69	39.68
animal	N	3	3	3	3	3
BNT162b1	%Diff	-6.7	-15.2	-18.1	-72.4	-22.7
Group 6:	Mean	89.33	54.97	236.03	3.00*	178.50
30 µg/	SD	4.89	21.21	90.68	0.00	79.72
animal	N	3	3	3	3	3
BNT162c1	%Diff	-9.9	-16.8	-32.5	-75.7	-15.9
Group 7:	Mean	91.33	59.53	285.53	7.37	151.70
100 µg/	SD	16.72	14.54	114.71	7.56	77.90
animal	N	3	3	3	3	3
BNT162b2	%Diff	-7.9	-9.9	-18.4	-40.3	-28.6

[a] - Anova & Dunnett: * = p ≤ 0.05

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a2]
Group 1: Control	Mean	109.77	92.47	447.53	14.57	365.60
	SD	20.35	19.99	87.14	16.21	74.22
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	59.07	84.57	432.77	6.67	258.53
	SD	50.08	26.63	188.55	3.25	225.11
	N	3	3	3	3	3
	%Diff	-46.2	-8.5	-3.3	-54.2	-29.3
Group 3: 10 µg/ animal BNT162a1	Mean	15.90	8.23*	14.73*	3.00	9.90
	SD	17.02	1.96	3.70	0.00	0.00
	N	3	3	3	3	3
	%Diff	-85.5	-91.1	-96.7	-79.4	-97.3
Group 4: 30 µg/ animal BNT162b1	Mean	22.10	22.13	93.40	3.00	68.67
	SD	30.92	26.04	139.95	0.00	101.79
	N	3	3	3	3	3
	%Diff	-79.9	-76.1	-79.1	-79.4	-81.2

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): * = p ≤ 0.05
[a2] - Anova & Dunnett(Log)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	44.97	39.23	166.93	7.50	121.87
100 µg/	SD	70.96	55.66	267.31	7.79	193.93
animal	N	3	3	3	3	3
BNT162b1	%Diff	-59.0	-57.6	-62.7	-48.5	-66.7
Group 6:	Mean	13.97	16.53	58.63	3.00	18.27
30 µg/	SD	17.26	3.87	26.57	0.00	14.49
animal	N	3	3	3	3	3
BNT162c1	%Diff	-87.3	-82.1	-86.9	-79.4	-95.0
Group 7:	Mean	19.27	16.93	50.83*	3.00	29.27
100 µg/	SD	26.44	17.03	66.22	0.00	33.54
animal	N	3	3	3	3	3
BNT162b2	%Diff	-82.4	-81.7	-88.6	-79.4	-92.0

[a] - Anova & Dunnett: * = $p \leq 0.05$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	88.43	56.80	269.07	4.50	220.07
	SD	19.95	20.82	111.47	2.60	106.23
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	117.03	75.83	377.60	3.00	191.67
	SD	20.22	18.32	79.12	0.00	56.91
	N	3	3	3	3	3
	%Diff	32.3	33.5	40.3	-33.3	-12.9
Group 3: 10 µg/ animal BNT162a1	Mean	109.40	61.53	344.33	9.10	200.20
	SD	27.17	17.01	107.63	7.04	40.67
	N	3	3	3	3	3
	%Diff	23.7	8.3	28.0	102.2	-9.0
Group 4: 30 µg/ animal BNT162b1	Mean	56.60	41.20	208.17	3.00	84.37
	SD	7.54	13.40	74.37	0.00	86.87
	N	3	3	3	3	3
	%Diff	-36.0	-27.5	-22.6	-33.3	-61.7

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	121.47	66.17	364.93	14.40	213.30
100 µg/	SD	12.48	16.50	103.43	10.58	48.88
animal	N	3	3	3	3	3
BNT162b1	%Diff	37.4	16.5	35.6	220.0	-3.1
Group 6:	Mean	110.80	55.23	292.13	4.77	159.30
30 µg/	SD	40.51	6.55	30.04	1.55	8.75
animal	N	3	3	3	3	3
BNT162c1	%Diff	25.3	-2.8	8.6	5.9	-27.6
Group 7:	Mean	92.20	54.60	291.13	7.60	156.00
100 µg/	SD	6.36	13.75	112.49	7.97	92.42
animal	N	3	3	3	3	3
BNT162b2	%Diff	4.3	-3.9	8.2	68.9	-29.1

[a] - Anova & Dunnett

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 10 Relative to Start Date (48h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	54.97 n	26.17 n	132.93 n	3.00 n	46.77 n
	SD	56.48	27.51	182.48	0.00	63.85
	N	3	3	3	3	3
		-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	84.90	66.80	269.17	3.00	178.57
	SD	61.87	52.44	231.66	0.00	147.46
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	55.63	87.87	362.97	4.63	167.80
	SD	78.85	80.06	383.08	2.83	273.49
	N	3	3	3	3	3
	%Diff	-34.5	31.5	34.8	54.4	-6.0
Group 3: 10 µg/ animal BNT162a1	Mean	4.00	7.10	12.60	3.00	9.90
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-95.3	-89.4	-95.3	0.0	-94.5
Group 4: 30 µg/ animal BNT162b1	Mean	44.80	35.77	145.90	3.00	81.00
	SD	45.08	46.23	230.88	0.00	123.15
	N	3	3	3	3	3
	%Diff	-47.2	-46.5	-45.8	0.0	-54.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	74.53	60.60	302.27	15.10	194.07
100 µg/	SD	63.43	47.90	264.90	11.03	164.25
animal	N	3	3	3	3	3
BNT162b1	%Diff	-12.2	-9.3	12.3	403.3	8.7
Group 7:	Mean	34.43	19.50	57.27	3.00	40.53
100 µg/	SD	32.49	18.80	77.36	0.00	53.06
animal	N	3	3	3	3	3
BNT162b2	%Diff	-59.4	-70.8	-78.7	0.0	-77.3

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	125.33	82.30	381.77	3.53	238.63
	SD	24.16	36.60	149.65	0.92	102.97
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	190.80*	112.80	499.80	3.00	270.73
	SD	35.23	26.42	83.83	0.00	13.59
	N	3	3	3	3	3
	%Diff	52.2	37.1	30.9	-15.1	13.5
Group 3: 10 µg/ animal BNT162a1	Mean	155.60	78.47	381.90	18.27**	225.57
	SD	34.68	18.13	124.92	7.18	54.72
	N	3	3	3	3	3
	%Diff	24.1	-4.7	0.0	417.0	-5.5
Group 4: 30 µg/ animal BNT162b1	Mean	124.07	102.80	471.40	5.37	234.17
	SD	18.46	27.35	129.00	2.05	107.20
	N	3	3	3	3	3
	%Diff	-1.0	24.9	23.5	51.9	-1.9

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	155.27	75.87	353.03	20.10**	233.80
100 µg/	SD	13.54	8.95	40.47	6.67	35.06
animal	N	3	3	3	3	3
BNT162b1	%Diff	23.9	-7.8	-7.5	468.9	-2.0
Group 7:	Mean	119.93	62.93	271.63	11.47	165.80
100 µg/	SD	24.61	12.34	68.69	2.91	35.65
animal	N	3	3	3	3	3
BNT162b2	%Diff	-4.3	-23.5	-28.8	224.5	-30.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a2]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	4.00	7.10	12.60	3.00	9.90
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	111.17*	25.20	69.83	3.00	9.90
	SD	16.10	23.53	84.67	0.00	0.00
	N	3	3	3	3	3
	%Diff	2679.2	254.9	454.2	0.0	0.0
Group 3: 10 µg/ animal BNT162a1	Mean	83.87	7.10	12.60	3.00	9.90
	SD	57.45	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	1996.7	0.0	0.0	0.0	0.0
Group 4: 30 µg/ animal BNT162b1	Mean	31.20	41.97	176.10	7.83	44.70
	SD	47.11	60.39	283.19	8.37	60.28
	N	3	3	3	3	3
	%Diff	680.0	491.1	1297.6	161.1	351.5

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank)
[a2] - Anova & Dunnett(Log)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Male		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	4.00	10.23	22.30	3.00	9.90
100 µg/	SD	0.00	5.43	16.80	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	0.0	44.1	77.0	0.0	0.0
Group 7:	Mean	43.17	44.40	214.23	7.40	106.50
100 µg/	SD	58.33	48.01	289.74	7.62	167.32
animal	N	3	3	3	3	3
BNT162b2	%Diff	979.2	525.4	1600.3	146.7	975.8

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	30.67	28.57	119.00	3.00	71.90
	SD	46.19	23.95	135.10	0.00	107.39
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.00	7.10	12.60	3.00 n	9.90
	SD	0.00	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-87.0	-75.1	-89.4	0.0	-86.2
Group 3: 10 µg/ animal BNT162a1	Mean	9.10	8.00	12.60	3.00 n	9.90
	SD	8.83	1.56	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-70.3	-72.0	-89.4	0.0	-86.2
Group 4: 30 µg/ animal BNT162b1	Mean	8.20	7.10	12.60	3.00 n	9.90
	SD	7.27	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-73.3	-75.1	-89.4	0.0	-86.2

[a] - Anova & Dunnett(Rank): n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	4.00	7.10	12.60	3.00 n	9.90
100 µg/	SD	0.00	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-87.0	-75.1	-89.4	0.0	-86.2
Group 6:	Mean	4.00	7.10	12.60	3.00 n	9.90
30 µg/	SD	0.00	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162c1	%Diff	-87.0	-75.1	-89.4	0.0	-86.2
Group 7:	Mean	22.03	18.43	58.80	3.00 n	43.40
100 µg/	SD	30.80	19.63	80.02	0.00	58.02
animal	N	3	3	3	3	3
BNT162b2	%Diff	-28.2	-35.5	-50.6	0.0	-39.6

[a] - Anova & Dunnett: n - Inappropriate for statistics

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	86.50	65.83	345.70	5.77	168.03
	SD	8.29	29.96	188.07	3.19	78.07
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	97.87	46.83	246.17	6.07	84.67
	SD	32.96	14.73	113.44	4.55	70.78
	N	3	3	3	3	3
	%Diff	13.1	-28.9	-28.8	5.2	-49.6
Group 3: 10 µg/ animal BNT162a1	Mean	86.40	51.03	260.87	3.00	114.70
	SD	19.75	11.57	62.68	0.00	26.97
	N	3	3	3	3	3
	%Diff	-0.1	-22.5	-24.5	-48.0	-31.7
Group 4: 30 µg/ animal BNT162b1	Mean	73.37	46.73	235.47	5.50	132.57
	SD	29.11	8.39	52.21	4.07	27.24
	N	3	3	3	3	3
	%Diff	-15.2	-29.0	-31.9	-4.6	-21.1

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 1 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	68.80	38.03	191.43	3.00	90.77
100 µg/	SD	11.61	4.62	36.49	0.00	33.29
animal	N	3	3	3	3	3
BNT162b1	%Diff	-20.5	-42.2	-44.6	-48.0	-46.0
Group 6:	Mean	104.33	67.03	298.10	4.27	209.23
30 µg/	SD	11.41	8.89	13.67	2.19	40.58
animal	N	3	3	3	3	3
BNT162c1	%Diff	20.6	1.8	-13.8	-26.0	24.5
Group 7:	Mean	88.10	52.83	268.23	3.43	182.03
100 µg/	SD	10.64	11.39	67.42	0.75	51.88
animal	N	3	3	3	3	3
BNT162b2	%Diff	1.8	-19.7	-22.4	-40.5	8.3

[a] - Anova & Dunnett

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	23.27	12.80	48.37	3.00	17.80
	SD	31.91	9.87	61.95	0.00	13.68
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	31.00	27.47	126.83	3.00 n	74.30
	SD	46.25	35.28	197.86	0.00	111.54
	N	3	3	3	3	3
	%Diff	33.2	114.6	162.2	0.0	317.4
Group 3: 10 µg/ animal BNT162a1	Mean	27.20	12.80	41.77	3.00 n	9.90
	SD	24.15	8.94	41.12	0.00	0.00
	N	3	3	3	3	3
	%Diff	16.9	0.0	-13.6	0.0	-44.4
Group 4: 30 µg/ animal BNT162b1	Mean	54.43	34.17	148.90	3.00 n	112.93
	SD	39.53	46.88	236.08	0.00	178.46
	N	3	3	3	3	3
	%Diff	134.0	166.9	207.9	0.0	534.5

[a] - Anova & Dunnett(Log)
[a1] - Anova & Dunnett(Rank): n - Inappropriate for statistics

FDA-CBER-2021-5683-0766724

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	44.73	35.73	156.30	3.00 n	105.33
100 µg/	SD	68.48	49.59	248.90	0.00	165.30
animal	N	3	3	3	3	3
BNT162b1	%Diff	92.3	179.2	223.2	0.0	491.8
Group 6:	Mean	9.50	7.50	12.60	3.00 n	9.90
30 µg/	SD	8.26	0.69	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162c1	%Diff	-59.2	-41.4	-73.9	0.0	-44.4
Group 7:	Mean	4.60	7.43	12.60	3.00 n	9.90
100 µg/	SD	1.04	0.58	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b2	%Diff	-80.2	-41.9	-73.9	0.0	-44.4

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	77.80	43.67	213.37	3.00	125.70
	SD	18.19	19.70	99.74	0.00	98.90
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	103.77	42.77	220.37	3.00	115.83
	SD	53.24	23.93	146.31	0.00	92.56
	N	3	3	3	3	3
	%Diff	33.4	-2.1	3.3	0.0	-7.8
Group 3: 10 µg/ animal BNT162a1	Mean	129.80	70.53	400.23	7.03	209.87
	SD	11.86	12.55	95.18	3.65	25.81
	N	3	3	3	3	3
	%Diff	66.8	61.5	87.6	134.4	67.0
Group 4: 30 µg/ animal BNT162b1	Mean	80.93	51.47	260.00	3.00	202.23
	SD	30.62	14.82	89.54	0.00	86.64
	N	3	3	3	3	3
	%Diff	4.0	17.9	21.9	0.0	60.9

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 8 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	118.27	77.73	445.93	4.67	240.53
100 µg/	SD	7.21	10.64	51.50	2.31	38.91
animal	N	3	3	3	3	3
BNT162b1	%Diff	52.0	78.0	109.0	55.6	91.4
Group 6:	Mean	164.30**	60.17	345.67	6.43	179.00
30 µg/	SD	17.38	13.33	109.37	2.47	85.78
animal	N	3	3	3	3	3
BNT162c1	%Diff	111.2	37.8	62.0	114.4	42.4
Group 7:	Mean	118.40	68.07	378.43	8.03	205.53
100 µg/	SD	24.66	13.95	92.07	4.74	37.46
animal	N	3	3	3	3	3
BNT162b2	%Diff	52.2	55.9	77.4	167.8	63.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 10 Relative to Start Date (48h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	80.67 n	7.10 n	12.60 n	3.00 n	9.90 n
	SD	49.37	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
		-	-	-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a2]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	37.33	26.27	116.57	3.00	66.90
	SD	57.74	33.20	180.08	0.00	98.73
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	79.63	60.53	252.57	3.00	148.53
	SD	23.68	39.81	182.59	0.00	120.84
	N	3	3	3	3	3
	%Diff	113.3	130.5	116.7	0.0	122.0
Group 3: 10 µg/ animal BNT162a1	Mean	55.60	42.73	179.63	12.23	101.57
	SD	62.22	48.76	243.56	15.99	158.77
	N	3	3	3	3	3
	%Diff	48.9	62.7	54.1	307.8	51.8
Group 4: 30 µg/ animal BNT162b1	Mean	34.30	7.10	12.60	3.00	9.90
	SD	36.98	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-8.1	-73.0	-89.2	0.0	-85.2

[a] - Anova & Dunnett(Log)
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0766729

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (PreDs)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	19.07	7.10	12.60	3.00	9.90
100 µg/	SD	26.10	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-48.9	-73.0	-89.2	0.0	-85.2
Group 7:	Mean	47.63	42.37	203.97	10.70	112.73
100 µg/	SD	66.67	61.08	331.46	13.34	178.11
animal	N	3	3	3	3	3
BNT162b2	%Diff	27.6	61.3	75.0	256.7	68.5

[a] - Anova & Dunnett

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a]
Group 1: Control	Mean	121.37	90.97	420.53	3.27	230.10
	SD	18.61	29.50	143.71	0.46	89.38
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	185.67	96.20	468.70	3.10	246.37
	SD	51.68	23.88	100.85	0.17	46.35
	N	3	3	3	3	3
	%Diff	53.0	5.8	11.5	-5.1	7.1
Group 3: 10 µg/ animal BNT162a1	Mean	158.37	72.50	344.87	13.27	213.67
	SD	27.58	1.15	40.45	9.35	5.06
	N	3	3	3	3	3
	%Diff	30.5	-20.3	-18.0	306.1	-7.1
Group 4: 30 µg/ animal BNT162b1	Mean	134.57	108.27	504.70	3.67	253.23
	SD	23.73	26.68	112.68	0.61	35.48
	N	3	3	3	3	3
	%Diff	10.9	19.0	20.0	12.2	10.1

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 15 Relative to Start Date (6 h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	133.50	97.77	488.37	19.00 *	277.20
100 µg/	SD	8.85	18.01	138.53	12.20	66.15
animal	N	3	3	3	3	3
BNT162b1	%Diff	10.0	7.5	16.1	481.6	20.5
Group 7:	Mean	112.23	64.93	314.80	11.37	186.23
100 µg/	SD	13.20	16.36	106.20	9.11	55.96
animal	N	3	3	3	3	3
BNT162b2	%Diff	-7.5	-28.6	-25.1	248.0	-19.1

[a] - Anova & Dunnett: * = p ≤ 0.05

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a1]	IL-1beta (pg/mL) [a1]	IL-6 (pg/mL) [a1]	IL-10 (pg/mL) [a1]
Group 1: Control	Mean	32.37	20.03	77.83	3.00	45.87
	SD	49.13	22.40	112.99	0.00	62.30
	N	3	3	3	3	3
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	143.07*	26.20	97.60	6.10	91.10
	SD	28.57	33.08	147.22	5.37	140.64
	N	3	3	3	3	3
	%Diff	342.0	30.8	25.4	103.3	98.6
Group 3: 10 µg/ animal BNT162a1	Mean	68.70	7.10	12.60	3.00	9.90
	SD	36.25	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	112.3	-64.6	-83.8	0.0	-78.4
Group 4: 30 µg/ animal BNT162b1	Mean	14.73	7.10	12.60	3.00	9.90
	SD	18.59	0.00	0.00	0.00	0.00
	N	3	3	3	3	3
	%Diff	-54.5	-64.6	-83.8	0.0	-78.4

[a] - Anova & Dunnett(Log): * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank)

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TABLE 9-1 Cytokine Levels - Summary Rat

Day: 17 Relative to Start Date (48h pa)

Sex: Female		Cytokine Levels				
		IFN-gamma (pg/mL) [a]	TNF-alpha (pg/mL) [a]	IL-1beta (pg/mL) [a]	IL-6 (pg/mL) [a]	IL-10 (pg/mL) [a]
Group 5:	Mean	10.43	11.40	24.87	3.00	9.90
100 µg/	SD	9.87	6.60	19.54	0.00	0.00
animal	N	3	3	3	3	3
BNT162b1	%Diff	-67.8	-43.1	-68.1	0.0	-78.4
Group 7:	Mean	4.70	7.10	12.60	3.00	9.90
100 µg/	SD	0.82	0.00	0.00	0.00	0.00
animal	N	3	3	3	3	3
BNT162b2	%Diff	-85.5	-64.6	-83.8	0.0	-78.4

[a] - Anova & Dunnett

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TABLE 9-1 Cytokine Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	1 (PreDs)	2	Male	IL-1beta	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	1 (PreDs)	2	Male	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	2	Male	IL-10	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	3	Male	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	3	Male	IL-10	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	4	Male	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	4	Male	IL-10	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	5	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	5	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	6	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	6	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	7	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	7	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (6 h pa)	3	Male	IL-6	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	1 (6 h pa)	6	Male	IL-6	*	Anova & Dunnett: * = p ≤ 0.05
	8 (PreDs)	3	Male	TNF-alpha	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	8 (PreDs)	3	Male	IL-1beta	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	8 (PreDs)	7	Male	IL-1beta	*	Anova & Dunnett: * = p ≤ 0.05
	10 (48h pa)	6	Male	IFN-gamma	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	TNF-alpha	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	IL-1beta	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Male	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	15 (6 h pa)	2	Male	IFN-gamma	*	Anova & Dunnett: * = p ≤ 0.05
	15 (6 h pa)	3	Male	IL-6	**	Anova & Dunnett: ** = p ≤ 0.01
	15 (6 h pa)	5	Male	IL-6	**	Anova & Dunnett: ** = p ≤ 0.01
	17 (48h pa)	2	Male	IFN-gamma	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 9-1 Cytokine Levels - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	1 (PreDs)	2	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	3	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	4	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	1 (PreDs)	5	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	6	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	1 (PreDs)	7	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (PreDs)	2	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	8 (PreDs)	3	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	8 (PreDs)	4	Female	IL-6	n	Anova & Dunnett(Rank): n - Inappropriate for statistics
	8 (PreDs)	5	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (PreDs)	6	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (PreDs)	7	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	8 (6 h pa)	6	Female	IFN-gamma	**	Anova & Dunnett: ** = $p \leq 0.01$
	10 (48h pa)	6	Female	IFN-gamma	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	TNF-alpha	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	IL-1beta	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	IL-6	n	Anova & Dunnett: n - Inappropriate for statistics
	10 (48h pa)	6	Female	IL-10	n	Anova & Dunnett: n - Inappropriate for statistics
	15 (6 h pa)	5	Female	IL-6	*	Anova & Dunnett: * = $p \leq 0.05$
	17 (48h pa)	2	Female	IFN-gamma	*	Anova & Dunnett(Log): * = $p \leq 0.05$

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
212	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
213	13.7	7.1 !	12.6 !	3.0 !	9.9 !
Mean	7.23	7.10	12.60	3.00	9.90
SD	5.60	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766737

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
218	4.0 !	14.7	15.1	3.0 !	9.9 !
219	4.0 !	24.7	59.9	3.0 !	9.9 !
Mean	4.00	15.50	29.20	3.00	9.90
SD	0.00	8.83	26.62	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766738

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
224	22.7	7.1 !	12.6 !	3.0 !	9.9 !
225	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	10.23	7.10	12.60	3.00	9.90
SD	10.80	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766739

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
230	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
231	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766740

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
236	4.8	7.1 !	12.6 !	3.0 !	9.9 !
237	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.27	7.10	12.60	3.00	9.90
SD	0.46	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766741

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
242	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
243	14.6	7.1 !	12.6 !	3.0 !	9.9 !
Mean	7.53	7.10	12.60	3.00	9.90
SD	6.12	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766742

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	8.7	7.1 !	12.6 !	3.0 !	9.9 !
248	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
249	4.0 !	7.9	12.6 !	3.0 !	9.9 !
Mean	5.57	7.37	12.60	3.00	9.90
SD	2.71	0.46	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766743

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	93.5	60.8	316.2	8.2	149.9
212	96.2	54.8	255.1	6.9	140.0
213	107.8	82.7	478.5	21.9	347.2
Mean	99.17	66.10	349.93	12.33	212.37
SD	7.60	14.69	115.46	8.31	116.87
N	3	3	3	3	3

FDA-CBER-2021-5683-0766744

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	148.7	88.0	505.9	11.9	304.4
218	136.5	106.3	552.2	5.5	99.9
219	85.2	68.3	335.6	3.0 !	69.5
Mean	123.47	87.53	464.57	6.80	157.93
SD	33.70	19.00	114.06	4.59	127.75
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766745

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	83.1	54.9	286.5	3.0 !	149.3
224	62.0	35.9	176.6	3.0 !	122.6
225	95.3	57.2	289.6	3.0 !	171.4
Mean	80.13	49.33	250.90	3.00	147.77
SD	16.85	11.69	64.36	0.00	24.44
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766746

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	94.8	63.4	338.3	9.6	153.5
230	80.3	71.9	389.4	10.4	231.1
231	72.1	58.0	314.7	7.6	187.7
Mean	82.40	64.43	347.47	9.20	190.77
SD	11.49	7.01	38.18	1.44	38.89
N	3	3	3	3	3

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	87.3	51.7	279.8	3.0 !	180.4
236	107.3	73.4	370.4	4.2	193.1
237	83.1	43.1	210.0	3.0 !	118.9
Mean	92.57	56.07	286.73	3.40	164.13
SD	12.93	15.61	80.42	0.69	39.68
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766748

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	90.4	32.6	143.3	3.0 !	97.9
242	93.6	57.5	240.3	3.0 !	180.3
243	84.0	74.8	324.5	3.0 !	257.3
Mean	89.33	54.97	236.03	3.00	178.50
SD	4.89	21.21	90.68	0.00	79.72
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766749

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 1 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	107.6	75.9	416.4	16.1	229.1
248	92.2	48.1	237.8	3.0 !	152.7
249	74.2	54.6	202.4	3.0 !	73.3
Mean	91.33	59.53	285.53	7.37	151.70
SD	16.72	14.54	114.71	7.56	77.90
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766750

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	90.7	71.5	349.6	3.0 !	279.9
212	107.4	94.6	476.5	7.6	408.8
213	131.2	111.3	516.5	33.1	408.1
Mean	109.77	92.47	447.53	14.57	365.60
SD	20.35	19.99	87.14	16.21	74.22
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766751

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	71.3	80.5	446.1	7.8	317.2
218	101.9	113.0	614.3	9.2	448.5
219	4.0 !	60.2	237.9	3.0 !	9.9 !
Mean	59.07	84.57	432.77	6.67	258.53
SD	50.08	26.63	188.55	3.25	225.11
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766752

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	7.3	7.1 !	12.6 !	3.0 !	9.9 !
224	4.9	7.1 !	12.6 !	3.0 !	9.9 !
225	35.5	10.5	19.0	3.0 !	9.9 !
Mean	15.90	8.23	14.73	3.00	9.90
SD	17.02	1.96	3.70	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766753

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
230	4.5	7.1 !	12.6 !	3.0 !	9.9 !
231	57.8	52.2	255.0	3.0 !	186.2
Mean	22.10	22.13	93.40	3.00	68.67
SD	30.92	26.04	139.95	0.00	101.79
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766754

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
236	126.9	103.5	475.6	16.5	345.8
237	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	44.97	39.23	166.93	7.50	121.87
SD	70.96	55.66	267.31	7.79	193.93
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766755

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	33.9	21.0	88.8	3.0 !	35.0
242	4.0 !	14.3	48.4	3.0 !	9.9 !
243	4.0 !	14.3	38.7	3.0 !	9.9 !
Mean	13.97	16.53	58.63	3.00	18.27
SD	17.26	3.87	26.57	0.00	14.49
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766756

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	49.8	36.6	127.3	3.0 !	68.0
248	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
249	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	19.27	16.93	50.83	3.00	29.27
SD	26.44	17.03	66.22	0.00	33.54
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766757

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	80.1	47.1	228.7	3.0 !	179.5
212	74.0	42.6	183.4	3.0 !	140.1
213	111.2	80.7	395.1	7.5	340.6
Mean	88.43	56.80	269.07	4.50	220.07
SD	19.95	20.82	111.47	2.60	106.23
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766758

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	116.1	59.1	297.4	3.0 !	192.6
218	137.7	73.0	379.8	3.0 !	248.1
219	97.3	95.4	455.6	3.0 !	134.3
Mean	117.03	75.83	377.60	3.00	191.67
SD	20.22	18.32	79.12	0.00	56.91
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766759

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	139.0	78.2	446.4	16.8	238.2
224	85.6	44.2	231.9	3.0 !	157.3
225	103.6	62.2	354.7	7.5	205.1
Mean	109.40	61.53	344.33	9.10	200.20
SD	27.17	17.01	107.63	7.04	40.67
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766760

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	58.8	37.7	188.8	3.0 !	9.9 !
230	62.8	56.0	290.3	3.0 !	179.8
231	48.2	29.9	145.4	3.0 !	63.4
Mean	56.60	41.20	208.17	3.00	84.37
SD	7.54	13.40	74.37	0.00	86.87
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766761

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	112.4	73.3	394.3	16.3	246.7
236	135.7	77.9	450.5	23.9	236.0
237	116.3	47.3	250.0	3.0 !	157.2
Mean	121.47	66.17	364.93	14.40	213.30
SD	12.48	16.50	103.43	10.58	48.88
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766762

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	109.8	49.2	261.2	3.0 !	164.4
242	151.8	62.2	321.2	5.9	149.2
243	70.8	54.3	294.0	5.4	164.3
Mean	110.80	55.23	292.13	4.77	159.30
SD	40.51	6.55	30.04	1.55	8.75
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766763

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 8 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	98.4	69.7	412.4	16.8	254.7
248	85.7	51.3	270.8	3.0 !	141.8
249	92.5	42.8	190.2	3.0 !	71.5
Mean	92.20	54.60	291.13	7.60	156.00
SD	6.36	13.75	112.49	7.97	92.42
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766764

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date (48h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
241	116.3	57.7	342.9	3.0 !	120.5
242	43.5	7.1 !	12.6 !	3.0 !	9.9 !
243	5.1	13.7	43.3	3.0 !	9.9 !
Mean	54.97	26.17	132.93	3.00	46.77
SD	56.48	27.51	182.48	0.00	63.85
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766765

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	130.6	105.4	463.0	3.0 !	283.1
212	109.6	87.9	331.9	3.0 !	242.7
213	14.5	7.1 !	12.6 !	3.0 !	9.9 !
Mean	84.90	66.80	269.17	3.00	178.57
SD	61.87	52.44	231.66	0.00	147.46
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766766

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	6.9	7.1 !	12.6 !	3.0 !	9.9 !
218	146.6	167.2	772.0	7.9	483.6
219	13.4	89.3	304.3	3.0 !	9.9 !
Mean	55.63	87.87	362.97	4.63	167.80
SD	78.85	80.06	383.08	2.83	273.49
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766767

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
224	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
225	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766768

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	37.2	11.1	12.6 !	3.0 !	9.9 !
230	93.2	89.1	412.5	3.0 !	223.2
231	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	44.80	35.77	145.90	3.00	81.00
SD	45.08	46.23	230.88	0.00	123.15
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766769

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	92.7	75.2	362.0	17.7	246.9
236	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
237	126.9	99.5	532.2	24.6	325.4
Mean	74.53	60.60	302.27	15.10	194.07
SD	63.43	47.90	264.90	11.03	164.25
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766770

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	69.9	41.2	146.6	3.0 !	101.8
248	6.1	8.1	12.6 !	3.0 !	9.9 !
249	27.3	9.2	12.6 !	3.0 !	9.9 !
Mean	34.43	19.50	57.27	3.00	40.53
SD	32.49	18.80	77.36	0.00	53.06
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766771

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	124.7	67.4	302.0	3.0 !	203.8
212	101.5	55.5	288.9	3.0 !	157.6
213	149.8	124.0	554.4	4.6	354.5
Mean	125.33	82.30	381.77	3.53	238.63
SD	24.16	36.60	149.65	0.92	102.97
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766772

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	230.7	91.6	419.3	3.0 !	260.3
218	164.0	104.4	493.5	3.0 !	265.8
219	177.7	142.4	586.6	3.0 !	286.1
Mean	190.80	112.80	499.80	3.00	270.73
SD	35.23	26.42	83.83	0.00	13.59
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766773

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	116.8	64.0	301.3	15.6	196.2
224	183.6	72.6	318.6	12.8	191.8
225	166.4	98.8	525.8	26.4	288.7
Mean	155.60	78.47	381.90	18.27	225.57
SD	34.68	18.13	124.92	7.18	54.72
N	3	3	3	3	3

FDA-CBER-2021-5683-0766774

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	135.9	102.5	477.2	6.6	181.6
230	133.5	130.3	597.4	6.5	357.5
231	102.8	75.6	339.6	3.0 !	163.4
Mean	124.07	102.80	471.40	5.37	234.17
SD	18.46	27.35	129.00	2.05	107.20
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766775

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	140.2	83.2	395.2	23.7	273.6
236	159.2	78.5	349.4	24.2	220.3
237	166.4	65.9	314.5	12.4	207.5
Mean	155.27	75.87	353.03	20.10	233.80
SD	13.54	8.95	40.47	6.67	35.06
N	3	3	3	3	3

FDA-CBER-2021-5683-0766776

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 15 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	92.3	49.2	197.1	12.4	165.7
248	139.5	73.1	332.4	13.8	201.5
249	128.0	66.5	285.4	8.2	130.2
Mean	119.93	62.93	271.63	11.47	165.80
SD	24.61	12.34	68.69	2.91	35.65
N	3	3	3	3	3

FDA-CBER-2021-5683-0766777

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
211	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
212	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
213	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766778

090177e194f4cf37\Approved\Approved On: 18-Sep-2020 13:38 (GMT)

TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
217	94.9	16.7	29.8	3.0 !	9.9 !
218	111.5	7.1 !	12.6 !	3.0 !	9.9 !
219	127.1	51.8	167.1	3.0 !	9.9 !
Mean	111.17	25.20	69.83	3.00	9.90
SD	16.10	23.53	84.67	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766779

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
223	22.9	7.1 !	12.6 !	3.0 !	9.9 !
224	137.0	7.1 !	12.6 !	3.0 !	9.9 !
225	91.7	7.1 !	12.6 !	3.0 !	9.9 !
Mean	83.87	7.10	12.60	3.00	9.90
SD	57.45	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766780

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
229	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
230	85.6	111.7	503.1	17.5	114.3
231	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	31.20	41.97	176.10	7.83	44.70
SD	47.11	60.39	283.19	8.37	60.28
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766781

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
235	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
236	4.0 !	16.5	41.7	3.0 !	9.9 !
237	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	10.23	22.30	3.00	9.90
SD	0.00	5.43	16.80	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766782

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date (48h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
247	110.2	99.8	547.6	16.2	299.7
248	4.0 !	15.0	23.1	3.0 !	9.9 !
249	15.3	18.4	72.0	3.0 !	9.9 !
Mean	43.17	44.40	214.23	7.40	106.50
SD	58.33	48.01	289.74	7.62	167.32
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766783

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	84.0	54.4	271.0	3.0 !	195.9
216	4.0 !	24.2	73.4	3.0 !	9.9 !
Mean	30.67	28.57	119.00	3.00	71.90
SD	46.19	23.95	135.10	0.00	107.39
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766784

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
221	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
222	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766785

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	19.3	9.8	12.6 !	3.0 !	9.9 !
227	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
228	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	9.10	8.00	12.60	3.00	9.90
SD	8.83	1.56	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766786

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
233	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
234	16.6	7.1 !	12.6 !	3.0 !	9.9 !
Mean	8.20	7.10	12.60	3.00	9.90
SD	7.27	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766787

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
239	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
240	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766788

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
245	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
246	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.00	7.10	12.60	3.00	9.90
SD	0.00	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766789

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	4.5	7.1 !	12.6 !	3.0 !	9.9 !
251	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
252	57.6	41.1	151.2	3.0 !	110.4
Mean	22.03	18.43	58.80	3.00	43.40
SD	30.80	19.63	80.02	0.00	58.02
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766790

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	77.0	38.9	190.9	3.4	83.6
215	92.3	60.5	291.2	4.5	237.6
216	90.2	98.1	555.0	9.4	182.9
Mean	86.50	65.83	345.70	5.77	168.03
SD	8.29	29.96	188.07	3.19	78.07
N	3	3	3	3	3

FDA-CBER-2021-5683-0766791

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	100.2	41.9	195.6	3.9	40.5
221	63.8	35.2	166.8	3.0 !	47.2
222	129.6	63.4	376.1	11.3	166.3
Mean	97.87	46.83	246.17	6.07	84.67
SD	32.96	14.73	113.44	4.55	70.78
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766792

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	71.9	55.0	270.3	3.0 !	103.9
227	108.9	60.1	318.3	3.0 !	145.4
228	78.4	38.0	194.0	3.0 !	94.8
Mean	86.40	51.03	260.87	3.00	114.70
SD	19.75	11.57	62.68	0.00	26.97
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766793

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	81.7	48.5	230.7	3.0 !	146.2
233	41.0	37.6	185.8	3.3	101.2
234	97.4	54.1	289.9	10.2	150.3
Mean	73.37	46.73	235.47	5.50	132.57
SD	29.11	8.39	52.21	4.07	27.24
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766794

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	67.0	34.3	168.3	3.0 !	76.6
239	81.2	43.2	233.5	3.0 !	128.8
240	58.2	36.6	172.5	3.0 !	66.9
Mean	68.80	38.03	191.43	3.00	90.77
SD	11.61	4.62	36.49	0.00	33.29
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766795

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	103.8	60.7	291.7	3.0 !	227.0
245	93.2	63.2	288.8	6.8	162.8
246	116.0	77.2	313.8	3.0 !	237.9
Mean	104.33	67.03	298.10	4.27	209.23
SD	11.41	8.89	13.67	2.19	40.58
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766796

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 1 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	99.6	65.9	345.8	4.3	237.8
251	78.6	45.0	223.7	3.0 !	173.1
252	86.1	47.6	235.2	3.0 !	135.2
Mean	88.10	52.83	268.23	3.43	182.03
SD	10.64	11.39	67.42	0.75	51.88
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766797

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	60.1	24.2	119.9	3.0 !	33.6
216	5.7	7.1 !	12.6 !	3.0 !	9.9 !
Mean	23.27	12.80	48.37	3.00	17.80
SD	31.91	9.87	61.95	0.00	13.68
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766798

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	84.4	68.2	355.3	3.0 !	203.1
221	4.6	7.1 !	12.6 !	3.0 !	9.9 !
222	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	31.00	27.47	126.83	3.00	74.30
SD	46.25	35.28	197.86	0.00	111.54
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766799

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	25.4	8.2	23.9	3.0 !	9.9 !
227	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
228	52.2	23.1	88.8	3.0 !	9.9 !
Mean	27.20	12.80	41.77	3.00	9.90
SD	24.15	8.94	41.12	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766800

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	89.7	88.3	421.5	3.0 !	319.0
233	11.7	7.1 !	12.6 !	3.0 !	9.9 !
234	61.9	7.1 !	12.6 !	3.0 !	9.9 !
Mean	54.43	34.17	148.90	3.00	112.93
SD	39.53	46.88	236.08	0.00	178.46
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766801

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	6.4	7.1 !	12.6 !	3.0 !	9.9 !
239	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
240	123.8	93.0	443.7	3.0 !	296.2
Mean	44.73	35.73	156.30	3.00	105.33
SD	68.48	49.59	248.90	0.00	165.30
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766802

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	5.5	7.1 !	12.6 !	3.0 !	9.9 !
245	19.0	8.3	12.6 !	3.0 !	9.9 !
246	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	9.50	7.50	12.60	3.00	9.90
SD	8.26	0.69	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766803

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
251	5.8	8.1	12.6 !	3.0 !	9.9 !
252	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.60	7.43	12.60	3.00	9.90
SD	1.04	0.58	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766804

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	86.4	56.6	270.2	3.0 !	183.4
215	56.9	21.0	98.2	3.0 !	11.5
216	90.1	53.4	271.7	3.0 !	182.2
Mean	77.80	43.67	213.37	3.00	125.70
SD	18.19	19.70	99.74	0.00	98.90
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766805

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	118.9	50.6	278.1	3.0 !	156.5
221	44.6	15.9	54.0	3.0 !	9.9 !
222	147.8	61.8	329.0	3.0 !	181.1
Mean	103.77	42.77	220.37	3.00	115.83
SD	53.24	23.93	146.31	0.00	92.56
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766806

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	131.2	83.9	503.1	10.1	238.5
227	140.9	68.7	382.3	8.0	202.7
228	117.3	59.0	315.3	3.0 !	188.4
Mean	129.80	70.53	400.23	7.03	209.87
SD	11.86	12.55	95.18	3.65	25.81
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766807

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	92.1	58.0	327.0	3.0 !	228.5
233	46.3	34.5	158.3	3.0 !	105.5
234	104.4	61.9	294.7	3.0 !	272.7
Mean	80.93	51.47	260.00	3.00	202.23
SD	30.62	14.82	89.54	0.00	86.64
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766808

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	110.2	81.6	450.5	7.3	245.2
239	120.5	85.9	495.0	3.0 !	276.9
240	124.1	65.7	392.3	3.7	199.5
Mean	118.27	77.73	445.93	4.67	240.53
SD	7.21	10.64	51.50	2.31	38.91
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766809

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	156.6	63.8	364.5	8.1	219.2
245	152.1	45.4	228.1	3.6	80.5
246	184.2	71.3	444.4	7.6	237.3
Mean	164.30	60.17	345.67	6.43	179.00
SD	17.38	13.33	109.37	2.47	85.78
N	3	3	3	3	3

FDA-CBER-2021-5683-0766810

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 8 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	95.8	54.1	297.9	12.4	162.6
251	144.7	82.0	478.8	8.7	231.6
252	114.7	68.1	358.6	3.0 !	222.4
Mean	118.40	68.07	378.43	8.03	205.53
SD	24.66	13.95	92.07	4.74	37.46
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766811

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date (48h pa)

Group 6: 30 µg/ animal BNT162c1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
244	137.0	7.1 !	12.6 !	3.0 !	9.9 !
245	44.9	7.1 !	12.6 !	3.0 !	9.9 !
246	60.1	7.1 !	12.6 !	3.0 !	9.9 !
Mean	80.67	7.10	12.60	3.00	9.90
SD	49.37	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766812

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	104.0	64.6	324.5	3.0 !	180.9
216	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	37.33	26.27	116.57	3.00	66.90
SD	57.74	33.20	180.08	0.00	98.73
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766813

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	104.0	96.9	382.5	3.0 !	231.6
221	78.2	66.7	331.4	3.0 !	204.1
222	56.7	18.0	43.8	3.0 !	9.9 !
Mean	79.63	60.53	252.57	3.00	148.53
SD	23.68	39.81	182.59	0.00	120.84
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766814

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	38.1	22.8	67.2	3.0 !	9.9 !
227	124.7	98.3	459.1	30.7	284.9
228	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	55.60	42.73	179.63	12.23	101.57
SD	62.22	48.76	243.56	15.99	158.77
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766815

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	23.4	7.1 !	12.6 !	3.0 !	9.9 !
233	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
234	75.5	7.1 !	12.6 !	3.0 !	9.9 !
Mean	34.30	7.10	12.60	3.00	9.90
SD	36.98	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766816

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	49.2	7.1 !	12.6 !	3.0 !	9.9 !
239	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
240	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	19.07	7.10	12.60	3.00	9.90
SD	26.10	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766817

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (PreDs)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	124.4	112.9	586.7	26.1	318.4
251	14.3	7.1 !	12.6 !	3.0 !	9.9 !
252	4.2	7.1 !	12.6 !	3.0 !	9.9 !
Mean	47.63	42.37	203.97	10.70	112.73
SD	66.67	61.08	331.46	13.34	178.11
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766818

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	139.7	118.6	565.1	3.8	330.2
215	102.5	59.9	277.7	3.0 !	158.3
216	121.9	94.4	418.8	3.0 !	201.8
Mean	121.37	90.97	420.53	3.27	230.10
SD	18.61	29.50	143.71	0.46	89.38
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766819

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	236.3	116.3	536.5	3.0 !	255.3
221	133.0	69.8	352.8	3.0 !	196.2
222	187.7	102.5	516.8	3.3	287.6
Mean	185.67	96.20	468.70	3.10	246.37
SD	51.68	23.88	100.85	0.17	46.35
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766820

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	150.6	73.4	391.2	15.5	211.0
227	189.0	72.9	316.6	21.3	219.5
228	135.5	71.2	326.8	3.0 !	210.5
Mean	158.37	72.50	344.87	13.27	213.67
SD	27.58	1.15	40.45	9.35	5.06
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766821

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	139.1	130.8	595.5	3.0 !	272.3
233	108.9	78.8	378.6	4.2	212.3
234	155.7	115.2	540.0	3.8	275.1
Mean	134.57	108.27	504.70	3.67	253.23
SD	23.73	26.68	112.68	0.61	35.48
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766822

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	123.7	77.1	328.8	13.4	207.7
239	135.9	106.1	558.4	10.6	284.5
240	140.9	110.1	577.9	33.0	339.4
Mean	133.50	97.77	488.37	19.00	277.20
SD	8.85	18.01	138.53	12.20	66.15
N	3	3	3	3	3

FDA-CBER-2021-5683-0766823

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 15 Relative to Start Date (6 h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	119.3	81.6	421.2	21.8	247.9
251	120.4	64.3	314.4	7.3	172.1
252	97.0	48.9	208.8	5.0	138.7
Mean	112.23	64.93	314.80	11.37	186.23
SD	13.20	16.36	106.20	9.11	55.96
N	3	3	3	3	3

FDA-CBER-2021-5683-0766824

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 1: Control	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
214	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
215	89.1	45.9	208.3	3.0 !	117.8
216	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	32.37	20.03	77.83	3.00	45.87
SD	49.13	22.40	112.99	0.00	62.30
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766825

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 2: 30 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
220	169.1	7.1 !	12.6 !	3.0 !	9.9 !
221	112.5	64.4	267.6	12.3	253.5
222	147.6	7.1 !	12.6 !	3.0 !	9.9 !
Mean	143.07	26.20	97.60	6.10	91.10
SD	28.57	33.08	147.22	5.37	140.64
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766826

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 3: 10 µg/ animal BNT162a1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
226	68.6	7.1 !	12.6 !	3.0 !	9.9 !
227	32.5	7.1 !	12.6 !	3.0 !	9.9 !
228	105.0	7.1 !	12.6 !	3.0 !	9.9 !
Mean	68.70	7.10	12.60	3.00	9.90
SD	36.25	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766827

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 4: 30 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
232	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
233	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
234	36.2	7.1 !	12.6 !	3.0 !	9.9 !
Mean	14.73	7.10	12.60	3.00	9.90
SD	18.59	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766828

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 5: 100 µg/ animal BNT162b1	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
238	21.8	8.1	14.6	3.0 !	9.9 !
239	5.5	19.0	47.4	3.0 !	9.9 !
240	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
Mean	10.43	11.40	24.87	3.00	9.90
SD	9.87	6.60	19.54	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766829

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date (48h pa)

Group 7: 100 µg/ animal BNT162b2	Cytokine Levels				
	IFN-gamma (pg/mL)	TNF-alpha (pg/mL)	IL-1beta (pg/mL)	IL-6 (pg/mL)	IL-10 (pg/mL)
250	5.6	7.1 !	12.6 !	3.0 !	9.9 !
251	4.0 !	7.1 !	12.6 !	3.0 !	9.9 !
252	4.5	7.1 !	12.6 !	3.0 !	9.9 !
Mean	4.70	7.10	12.60	3.00	9.90
SD	0.82	0.00	0.00	0.00	0.00
N	3	3	3	3	3

! = Result Comment

FDA-CBER-2021-5683-0766830

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Page	Day	Group	Sex	Subject	Measurement	Type	Comments and Markers
	1 (PreDs)	1	Male	211	IFN-gamma	Result	
				Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	TNF-alpha	Result	
				Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	IL-1beta	Result	
				Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	IL-6	Result	
				Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	211	IL-10	Result	
				Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IFN-gamma	Result	
				Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	TNF-alpha	Result	
				Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IL-1beta	Result	
				Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IL-6	Result	
				Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	212	IL-10	Result	
				Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	TNF-alpha	Result	
				Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	IL-1beta	Result	
				Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	IL-6	Result	
				Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Male	213	IL-10	Result	
				Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			

FDA-CBER-2021-5683-0766831

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	2	Male	217	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	217	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	218	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	218	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	219	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

FDA-CBER-2021-5683-0766832

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	230	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Male	231	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	5	Male	235	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	235	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	236	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Male	237	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	6	Male	241	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	241	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	242	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Male	243	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	247	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	247	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	7	Male	247	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	247	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Male	249	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (6 h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (6 h pa)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Male	219	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	230	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	4	Male	230	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	230	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	235	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	5	Male	237	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
				Comments and Markers			
	8 (PreDs)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	242	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	242	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	243	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Male	243	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	247	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Male	249	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	7	Male	249	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	7	Male	249	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	7	Male	249	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	7	Male	249	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (6 h pa)	1	Male	211	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	1	Male	212	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	2	Male	217	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	2	Male	218	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	2	Male	219	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	3	Male	224	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Male	229	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Male	229	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Male	230	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Male	231	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (6 h pa)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	241	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	242	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	243	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Male	243	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	213	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	1	Male	213	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	213	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Male	213	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	217	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	3	Male	224	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	230	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	4	Male	231	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Male	231	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Male	236	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	247	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	248	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	7	Male	249	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	249	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Male	249	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	211	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	1	Male	212	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	212	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Male	213	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	217	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	217	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	218	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	218	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	2	Male	218	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	218	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	219	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Male	219	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	223	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	224	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	225	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	225	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	3	Male	225	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Male	225	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	229	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	4	Male	231	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	5	Male	235	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	235	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	236	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	236	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	236	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Male	237	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	7	Male	248	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Male	248	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Male	248	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	7	Male	249	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	17 (48h pa)	7	Male	249	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Page	Day	Group	Sex	Subject	Measurement	Type	Comments and Markers
	1 (PreDs)	1	Female	214	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	214	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	214	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	214	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	214	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	215	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	216	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	216	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	1	Female	216	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	2	Female	220	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	2	Female	220	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	2	Female	220	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	2	Female	220	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	2	Female	220	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	2	Female	221	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	221	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	226	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	227	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	3	Female	227	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	227	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	227	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	228	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	228	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	228	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	3	Female	228	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	232	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	232	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	232	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	232	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	4	Female	233	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	233	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	233	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	233	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	233	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	234	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	234	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	234	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	4	Female	234	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	238	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	238	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	238	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	238	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	5	Female	239	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	239	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	5	Female	240	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	6	Female	244	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	6	Female	244	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	245	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	245	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	245	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	245	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	245	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	246	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	246	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	246	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	246	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	1 (PreDs)	6	Female	246	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	1 (PreDs)	7	Female	250	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	1 (PreDs)	7	Female	250	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	1 (PreDs)	7	Female	250	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (PreDs)	7	Female	250	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	1 (PreDs)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	1 (6 h pa)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Female	244	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	1 (6 h pa)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	216	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	216	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	1	Female	216	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	220	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	221	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	221	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	221	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	221	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	222	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	222	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	222	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	222	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	2	Female	222	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	3	Female	226	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	3	Female	226	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	3	Female	227	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	3	Female	227	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	227	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	3	Female	228	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	233	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	234	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	234	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	4	Female	234	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	4	Female	234	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	238	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	239	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	8 (PreDs)	5	Female	240	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (PreDs)	6	Female	244	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	8 (PreDs)	6	Female	244	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	8 (PreDs)	6	Female	244	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	6	Female	244	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	245	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	245	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	245	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	6	Female	246	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	250	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (PreDs)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (PreDs)	7	Female	252	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	8 (6 h pa)	2	Female	221	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	8 (6 h pa)	2	Female	222	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	3	Female	228	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Female	232	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Female	233	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	4	Female	234	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	5	Female	239	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	8 (6 h pa)	7	Female	252	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	244	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	245	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	245	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	10 (48h pa)	6	Female	245	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	10 (48h pa)	6	Female	245	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	10 (48h pa)	6	Female	246	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	1	Female	216	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	3	Female	228	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	232	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	4	Female	232	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	232	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	233	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	4	Female	234	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	238	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	238	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	238	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	239	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	5	Female	240	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	251	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	15 (PreDs)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12,6 pg/mL). Set to 12,6 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (PreDs)	7	Female	252	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	2	Female	221	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	15 (6 h pa)	4	Female	232	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	1	Female	214	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	214	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	215	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	1	Female	216	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	220	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	222	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	2	Female	222	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	222	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	2	Female	222	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	226	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	227	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	228	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	228	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	3	Female	228	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	3	Female	228	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	232	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	232	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	232	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	232	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	232	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	233	IFN-gamma	Result	
			Comment:	Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	233	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	233	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	233	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	233	IL-10	Result	
			Comment:	Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	234	TNF-alpha	Result	
			Comment:	Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	234	IL-1beta	Result	
			Comment:	Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.			
	17 (48h pa)	4	Female	234	IL-6	Result	
			Comment:	Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.			

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	4	Female	234	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	238	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	238	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	239	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	239	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	5	Female	240	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	250	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 9-2 Cytokine Levels - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17 (48h pa)	7	Female	251	IFN-gamma	Result	
	Comment: Value below lowest level of quantification (= 4.0 pg/mL). Set to 4.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	251	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	251	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	251	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	251	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	252	TNF-alpha	Result	
	Comment: Value below lowest level of quantification (= 7.1 pg/mL). Set to 7.1 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	252	IL-1beta	Result	
	Comment: Value below lowest level of quantification (= 12.6 pg/mL). Set to 12.6 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	252	IL-6	Result	
	Comment: Value below lowest level of quantification (= 3.0 pg/mL). Set to 3.0 pg/mL for mean value calculation.						
	17 (48h pa)	7	Female	252	IL-10	Result	
	Comment: Value below lowest level of quantification (= 9.9 pg/mL). Set to 9.9 pg/mL for mean value calculation.						

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TABLE 10-1 Urinalysis - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0385 n	6.94 n	37.00 n
	SD	0.0130	0.42	12.32
	N	10	10	10
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0309	6.55	45.80
	SD	0.0057	0.20	5.62
	N	10	10	10
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0377	6.82	43.72
	SD	0.0109	0.40	13.40
	N	10	10	10
	%Diff	0.7	4.1	-4.5
Group 3: 10 µg/ animal BNT162a1	Mean	1.0355	6.77	38.80
	SD	0.0050	0.23	7.32
	N	10	10	10
	%Diff	0.4	3.4	-15.3
Group 4: 30 µg/ animal BNT162b1	Mean	1.0445**	6.62	30.81**
	SD	0.0081	0.26	6.55
	N	10	10	10
	%Diff	1.3	1.1	-32.7

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett: ** = p ≤ 0.01

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0458**	6.62	33.79*
	SD	0.0145	0.32	9.05
	N	10	10	10
	%Diff	1.4	1.1	-26.2
Group 7: 100 µg/ animal BNT162b2	Mean	1.0463**	6.35	31.67**
	SD	0.0122	0.27	9.65
	N	10	10	10
	%Diff	1.5	-3.1	-30.9

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

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TABLE 10-1 Urinalysis - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0694 n	6.42 n	19.38 n
	SD	0.0218	0.43	9.47
	N	5	5	5
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0374	6.90	27.59
	SD	0.0054	0.29	8.85
	N	5	5	5
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0384	6.68	28.00
	SD	0.0065	0.32	5.30
	N	5	5	5
	%Diff	0.1	-3.2	1.5
Group 3: 10 µg/ animal BNT162a1	Mean	1.0424	6.56	29.80
	SD	0.0170	0.27	7.62
	N	5	5	5
	%Diff	0.5	-4.9	8.0
Group 4: 30 µg/ animal BNT162b1	Mean	1.0538	6.56	25.98
	SD	0.0248	0.30	14.86
	N	5	5	5
	%Diff	1.6	-4.9	-5.8

[a] - Anova & Dunnett(Rank)
[a1] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5:	Mean	1.0494	6.74	25.73
100 µg/	SD	0.0158	0.15	11.11
animal	N	5	5	5
BNT162b1	%Diff	1.2	-2.3	-6.7
Group 7:	Mean	1.0352	6.74	34.74
100 µg/	SD	0.0026	0.34	4.99
animal	N	5	5	5
BNT162b2	%Diff	-0.2	-2.3	25.9

[a] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0377 n	6.46 n	47.65 n
	SD	0.0130	0.33	15.30
	N	10	10	10
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0349	6.26	45.54
	SD	0.0047	0.26	10.71
	N	10	10	10
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0391	6.39	48.55
	SD	0.0177	0.28	21.35
	N	10	10	10
	%Diff	0.4	2.1	6.6
Group 3: 10 µg/ animal BNT162a1	Mean	1.0408	6.27	42.62
	SD	0.0129	0.18	13.71
	N	10	10	10
	%Diff	0.6	0.2	-6.4
Group 4: 30 µg/ animal BNT162b1	Mean	1.0555**	6.15	32.31
	SD	0.0199	0.28	11.72
	N	10	10	10
	%Diff	2.0	-1.8	-29.1

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0464	6.27	38.55
	SD	0.0157	0.21	13.43
	N	10	10	10
	%Diff	1.1	0.2	-15.4
Group 7: 100 µg/ animal BNT162b2	Mean	1.0400	6.26	38.35
	SD	0.0099	0.20	15.62
	N	10	10	10
	%Diff	0.5	0.0	-15.8

[a] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 6: 30 µg/ animal BNT162c1	Mean	1.0406 n	6.18 n	30.70 n
	SD	0.0081	0.39	5.74
	N	5	5	5
		-	-	-

[a] - Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a1]	Urine Volume - relative - (mL/kg b.w./24 h) [a1]
Group 1: Control	Mean	1.0484	6.06	35.81
	SD	0.0316	0.38	19.38
	N	5	5	5
	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.0504	6.16	27.90
	SD	0.0208	0.53	15.15
	N	5	5	5
	%Diff	0.2	1.7	-22.1
Group 3: 10 µg/ animal BNT162a1	Mean	1.0410	6.24	28.12
	SD	0.0074	0.11	9.35
	N	5	5	5
	%Diff	-0.7	3.0	-21.5
Group 4: 30 µg/ animal BNT162b1	Mean	1.0542	6.26	26.63
	SD	0.0256	0.38	14.99
	N	5	5	5
	%Diff	0.6	3.3	-25.6

[a] - Anova & Dunnett(Rank)
[a1] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Urinalysis		
		Specific Gravity (g/mL) [a]	pH [a]	Urine Volume - relative - (mL/kg b.w./24 h) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.0474	6.48	28.22
	SD	0.0174	0.31	17.07
	N	5	5	5
	%Diff	-0.1	6.9	-21.2
Group 7: 100 µg/ animal BNT162b2	Mean	1.0432	6.28	29.37
	SD	0.0151	0.29	6.47
	N	5	5	5
	%Diff	-0.5	3.6	-18.0

[a] - Anova & Dunnett

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TABLE 10-1 Urinalysis - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Male	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Male	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics
	17	4	Male	Specific Gravity	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Urine Volume - relative -	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Specific Gravity	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Urine Volume - relative -	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Specific Gravity	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Urine Volume - relative -	**	Anova & Dunnett: ** = p ≤ 0.01
	31	6	Male	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Male	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-1 Urinalysis - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	10	6	Female	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	10	6	Female	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics
	17	4	Female	Specific Gravity	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	31	6	Female	Specific Gravity	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	pH	n	Anova & Dunnett: n - Inappropriate for statistics
	31	6	Female	Urine Volume - relative -	n	Anova & Dunnett: n - Inappropriate for statistics

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
151	SC	1.032	6.8	6.6	34.7
152	LC	1.052	6.6	5.1	23.2
153	LC	1.058	6.3	3.5	18.7
154	SC	1.025	7.2	9.9	48.2
155	SC	1.029	7.4	10.0	47.4
156	SC	1.034	7.0	7.3	36.8
157	SC	1.027	7.3	12.6	57.2
158	SC	1.042	7.1	6.8	37.4
159	SC	1.028	7.4	8.8	42.2
160	LC	1.058	6.3	4.4	24.0
Mean	-	1.0385	6.94	7.50	37.00
SD	-	0.0130	0.42	2.84	12.32
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
1	SC	1.026	6.6	12.0	51.3
2	SC	1.044	6.5	7.9	34.3
3	SC	1.028	6.4	11.1	44.2
4	SC	1.024	7.0	11.8	48.9
5	SC	1.034	6.6	10.5	44.8
6	SC	1.034	6.3	11.3	44.9
7	SC	1.030	6.6	11.8	49.8
8	SC	1.033	6.4	10.4	42.7
9	SC	1.029	6.7	10.7	42.7
10	SC	1.027	6.4	13.4	54.4
Mean	-	1.0309	6.55	11.09	45.80
SD	-	0.0057	0.20	1.43	5.62
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
31	SC	1.030	6.7	7.5	38.6
32	SC	1.032	7.3	9.4	48.0
33	LC	1.060	6.0	5.2	24.4
34	SC	1.031	7.0	9.2	45.4
35	SC	1.031	7.0	12.2	59.7
36	SC	1.037	6.8	8.1	40.4
37	LC	1.045	7.1	6.5	32.0
38	SC	1.029	7.1	12.9	61.8
39	LC	1.052	6.3	4.9	28.2
40	SC	1.030	6.9	11.5	58.7
Mean	-	1.0377	6.82	8.74	43.72
SD	-	0.0109	0.40	2.82	13.40
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
61	SC	1.032	7.1	9.8	39.0
62	SC	1.032	7.1	9.1	42.0
63	SC	1.038	6.8	9.7	38.9
64	LC	1.039	6.7	8.6	37.0
65	LC	1.038	6.7	7.3	30.8
66	SC	1.030	7.0	10.3	44.5
67	SC	1.028	6.7	11.3	44.3
68	LC	1.045	6.5	4.9	24.8
69	SC	1.036	6.5	11.3	50.6
70	SC	1.037	6.6	8.9	36.1
Mean	-	1.0355	6.77	9.12	38.80
SD	-	0.0050	0.23	1.92	7.32
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
91	LC	1.050	6.4	5.5	25.1
92	LC	1.060	6.5	5.3	25.2
93	LC	1.049	6.5	5.3	24.6
94	SC	1.035	6.6	8.2	38.5
95	LC	1.045	6.6	5.7	26.2
96	SC	1.030	7.3	10.1	43.0
97	SC	1.043	6.7	7.9	36.5
98	SC	1.044	6.4	6.7	31.2
99	LC	1.045	6.6	6.0	26.3
100	SC	1.044	6.6	6.7	31.6
Mean	-	1.0445	6.62	6.74	30.81
SD	-	0.0081	0.26	1.57	6.55
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
121	SC	1.039	6.9	9.0	37.6
122	SC	1.041	6.5	6.9	34.9
123	SC	1.038	7.0	7.2	32.8
124	SC	1.038	6.7	7.7	29.8
125	SC	1.034	6.9	10.2	49.2
126	LC	1.064	6.4	6.5	27.1
127	SC	1.035	6.6	7.8	37.2
128	SC	1.063	6.2	5.0	25.7
129	LC	1.072	6.1	4.0	18.8
130	SC	1.034	6.9	9.5	44.8
Mean	-	1.0458	6.62	7.38	33.79
SD	-	0.0145	0.32	1.93	9.05
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
181	LC	1.048	6.1	4.7	19.9
182	LC	1.049	6.2	5.5	28.0
183	LC	1.070	6.0	4.0	18.7
184	LC	1.054	6.4	5.4	26.3
185	SC	1.035	6.6	9.3	40.0
186	LC	1.060	6.2	6.4	33.0
187	SC	1.037	6.4	8.0	37.6
188	LC	1.041	6.2	5.1	24.1
189	SC	1.036	6.5	9.2	44.7
190	SC	1.033	6.9	9.5	44.2
Mean	-	1.0463	6.35	6.71	31.67
SD	-	0.0122	0.27	2.10	9.65
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
161	LC	1.082	6.1	3.1	11.2
162	LC	1.092	6.1	3.6	14.9
163	LC	1.064	7.1	5.9	20.6
164	SC	1.035	6.6	9.1	35.2
165	LC	1.074	6.2	4.3	14.9
Mean	-	1.0694	6.42	5.20	19.38
SD	-	0.0218	0.43	2.42	9.47
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
11	SC	1.045	6.8	6.1	21.5
12	SC	1.035	6.7	9.3	32.3
13	SC	1.034	6.9	10.0	33.9
14	SC	1.032	7.4	9.5	35.2
15	SC	1.041	6.7	4.5	15.1
Mean	-	1.0374	6.90	7.88	27.59
SD	-	0.0054	0.29	2.44	8.85
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
41	SC	1.037	6.3	7.0	26.7
42	SC	1.047	6.6	5.5	20.6
43	SC	1.034	7.1	10.6	34.5
44	SC	1.031	6.9	7.3	26.6
45	SC	1.043	6.5	8.9	31.6
Mean	-	1.0384	6.68	7.86	28.00
SD	-	0.0065	0.32	1.95	5.30
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
71	SC	1.025	6.6	12.0	40.2
72	SC	1.070	6.5	5.6	20.7
73	SC	1.045	6.4	6.5	24.3
74	SC	1.036	7.0	10.2	32.8
75	SC	1.036	6.3	10.0	31.0
Mean	-	1.0424	6.56	8.86	29.80
SD	-	0.0170	0.27	2.70	7.62
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
101	SC	1.032	6.8	12.4	47.5
102	SC	1.045	6.7	4.5	16.7
103	SC	1.034	6.8	11.4	34.2
104	SC	1.068	6.4	6.1	21.3
105	LC	1.090	6.1	3.0	10.3
Mean	-	1.0538	6.56	7.48	25.98
SD	-	0.0248	0.30	4.20	14.86
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
131	SC	1.037	6.8	7.5	24.4
132	SC	1.060	6.9	5.5	20.2
133	SC	1.062	6.7	6.2	23.7
134	SC	1.028	6.8	13.0	44.6
135	LC	1.060	6.5	4.3	15.7
Mean	-	1.0494	6.74	7.30	25.73
SD	-	0.0158	0.15	3.39	11.11
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
191	SC	1.032	7.2	11.0	40.9
192	SC	1.039	6.9	7.7	27.0
193	SC	1.036	6.3	10.5	35.4
194	SC	1.035	6.7	9.0	36.0
195	SC	1.034	6.6	10.0	34.4
Mean	-	1.0352	6.74	9.64	34.74
SD	-	0.0026	0.34	1.31	4.99
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
151	0	0	+++	0	0	0
152	0	0	+++	0	0	0
153	+	0	+++	0	0	0
154	0	0	+++	0	0	0
155	0	0	+++	0	0	0
156	0	0	+++	0	0	0
157	0	0	+++	0	0	0
158	0	0	+++	0	0	0
159	0	0	+++	0	0	0
160	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
1	0	0	++	0	0	0
2	0	+	+++	0	0	0
3	0	0	0	0	0	0
4	+	0	+	0	0	0
5	0	0	0	0	0	0
6	0	0	+	0	0	0
7	0	0	+	0	0	0
8	+	0	0	0	0	0
9	0	+	0	0	0	0
10	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
31	0	0	++	0	0	0
32	0	0	+++	0	0	0
33	0	0	0	0	0	0
34	0	+	+++	0	0	0
35	0	0	+++	0	0	0
36	0	0	+++	0	0	0
37	0	0	+++	0	0	0
38	0	0	++	0	0	0
39	0	0	++	0	0	0
40	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
61	0	0	+++	0	0	0
62	0	0	+++	0	0	0
63	0	0	+++	0	0	0
64	0	0	+++	0	0	0
65	0	0	+++	0	0	0
66	0	0	+++	0	0	0
67	0	0	+++	0	0	0
68	0	0	+++	0	0	0
69	0	0	++	0	0	0
70	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
91	0	0	+++	0	0	0
92	0	0	+++	0	0	0
93	0	0	+++	0	0	0
94	0	0	+	0	0	0
95	0	0	+++	0	0	0
96	0	0	++	0	0	0
97	0	0	+++	0	0	0
98	0	0	++	0	0	0
99	0	0	+++	0	0	0
100	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
121	0	0	+++	0	0	0
122	0	0	++	0	0	0
123	0	0	+++	0	0	0
124	0	0	++	0	0	0
125	0	0	++	0	0	0
126	0	0	+++	0	0	0
127	0	0	++	0	0	0
128	0	0	++	0	0	0
129	0	0	+	0	0	0
130	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
181	0	0	0	0	0	0
182	0	0	0	0	0	0
183	+	0	0	+	0	0
184	+	0	++	0	0	0
185	0	0	+++	0	0	0
186	+	0	++	0	0	0
187	0	0	0	0	0	0
188	0	0	0	0	0	0
189	0	0	++	0	0	0
190	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
161	+	0	0	0	0	0
162	0	0	+++	0	0	0
163	0	0	+++	0	0	0
164	0	0	++	0	0	0
165	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
11	0	0	+++	0	0	0
12	0	0	++	0	0	0
13	0	0	+++	0	0	0
14	0	0	+++	0	0	0
15	+	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
41	0	+	+++	0	0	0
42	0	0	+++	0	0	0
43	0	0	+++	0	0	0
44	0	0	+++	0	0	0
45	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
71	0	0	+	0	0	0
72	0	0	+++	0	0	0
73	0	0	+	0	0	0
74	0	0	+++	0	0	0
75	0	+	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
101	0	0	0	0	0	0
102	+	0	+++	+	0	0
103	0	0	+++	0	0	0
104	0	0	+++	0	0	0
105	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
131	0	0	+++	0	0	0
132	0	0	+++	0	0	0
133	0	0	+++	0	0	0
134	0	0	+++	0	0	0
135	0	0	+++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
191	0	0	++	0	0	0
192	0	+	+++	0	0	0
193	++	0	0	0	0	0
194	0	0	++	0	0	0
195	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
151	pos	0.3	normal	neg	normal	neg	10
152	pos	0.3	normal	neg	normal	neg	10
153	neg	0.3	normal	neg	normal	neg	10
154	pos	0.3	normal	neg	normal	neg	10
155	neg	0.3	normal	neg	normal	neg	neg
156	pos	0.3	normal	neg	normal	neg	10
157	pos	0.3	normal	neg	normal	neg	neg
158	neg	0.3	normal	neg	normal	neg	neg
159	pos	0.3	normal	neg	normal	neg	neg
160	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
1	pos	neg	normal	neg	normal	neg	neg
2	neg	0.3	normal	neg	normal	neg	neg
3	pos	neg	normal	neg	normal	neg	neg
4	pos	0.3	normal	neg	normal	neg	10
5	neg	0.3	normal	neg	normal	neg	10
6	pos	0.3	normal	neg	normal	neg	neg
7	pos	neg	normal	neg	normal	neg	neg
8	pos	neg	normal	neg	normal	neg	neg
9	pos	neg	normal	neg	normal	neg	neg
10	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
31	pos	0.3	normal	neg	normal	neg	10
32	pos	0.3	normal	neg	normal	neg	250
33	neg	0.3	normal	neg	normal	neg	10
34	pos	0.3	normal	neg	normal	neg	10
35	pos	0.3	normal	neg	normal	neg	neg
36	pos	0.3	normal	neg	normal	neg	10
37	pos	0.3	normal	neg	normal	neg	10
38	pos	0.3	normal	neg	normal	neg	neg
39	neg	0.3	normal	neg	normal	neg	neg
40	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
61	pos	0.3	normal	neg	normal	neg	neg
62	pos	0.3	normal	neg	normal	neg	neg
63	neg	0.3	normal	neg	normal	neg	neg
64	neg	0.3	normal	neg	normal	neg	neg
65	neg	0.3	normal	neg	normal	neg	neg
66	pos	0.3	normal	neg	normal	neg	neg
67	pos	neg	normal	neg	normal	neg	neg
68	neg	0.3	normal	neg	normal	neg	neg
69	pos	0.3	normal	neg	normal	neg	neg
70	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
91	pos	0.3	normal	neg	normal	neg	10
92	neg	0.3	normal	neg	normal	neg	neg
93	neg	0.3	normal	neg	normal	neg	25
94	pos	0.3	normal	neg	normal	neg	neg
95	neg	0.3	normal	neg	normal	neg	neg
96	pos	0.3	normal	neg	normal	neg	neg
97	pos	0.3	normal	neg	normal	neg	neg
98	neg	0.3	normal	neg	normal	neg	10
99	neg	0.3	normal	neg	normal	neg	10
100	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
121	pos	0.3	normal	neg	normal	neg	neg
122	pos	0.3	normal	neg	normal	neg	10
123	neg	0.3	normal	neg	normal	neg	neg
124	pos	0.3	normal	neg	normal	neg	neg
125	pos	0.3	normal	neg	normal	neg	neg
126	neg	5.0	normal	neg	normal	neg	10
127	pos	0.3	normal	neg	normal	neg	neg
128	neg	1.0	normal	neg	normal	neg	neg
129	neg	1.0	normal	neg	normal	neg	neg
130	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
181	neg	0.3	normal	neg	normal	neg	neg
182	neg	0.3	normal	neg	normal	neg	neg
183	neg	5.0	normal	neg	normal	neg	10
184	neg	0.3	normal	neg	normal	neg	10
185	pos	0.3	normal	neg	normal	neg	neg
186	neg	1.0	normal	neg	normal	neg	10
187	neg	0.3	normal	neg	normal	neg	neg
188	pos	0.3	normal	neg	normal	neg	10
189	pos	0.3	normal	neg	normal	neg	neg
190	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
161	neg	0.3	normal	neg	normal	neg	neg
162	neg	0.3	normal	neg	normal	neg	10
163	neg	0.3	normal	neg	normal	neg	neg
164	pos	0.3	normal	neg	normal	neg	neg
165	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
11	neg	0.3	normal	neg	normal	neg	neg
12	pos	0.3	normal	neg	normal	neg	neg
13	neg	0.3	normal	neg	normal	neg	neg
14	pos	0.3	normal	neg	normal	neg	neg
15	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
41	pos	0.3	normal	neg	normal	neg	neg
42	pos	0.3	normal	neg	normal	neg	neg
43	pos	0.3	normal	neg	normal	neg	neg
44	neg	0.3	normal	neg	normal	neg	neg
45	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
71	neg	0.3	normal	neg	normal	neg	neg
72	neg	0.3	normal	neg	normal	neg	neg
73	neg	0.3	normal	neg	normal	neg	neg
74	pos	0.3	normal	neg	normal	neg	10
75	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
101	neg	0.3	normal	neg	normal	neg	neg
102	pos	0.3	normal	neg	normal	neg	neg
103	pos	0.3	normal	neg	normal	neg	neg
104	neg	0.3	normal	neg	normal	neg	neg
105	neg	1.0	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
131	pos	1.0	normal	neg	normal	neg	neg
132	neg	0.3	normal	neg	normal	neg	neg
133	neg	0.3	normal	neg	normal	neg	neg
134	pos	0.3	normal	neg	normal	neg	neg
135	neg	0.3	normal	neg	normal	neg	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
191	pos	0.3	normal	neg	normal	neg	neg
192	neg	1.0	normal	neg	normal	neg	neg
193	pos	0.3	normal	neg	normal	neg	neg
194	neg	0.3	normal	neg	normal	neg	neg
195	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
166	LC	1.064	6.2	4.9	33.4
167	SC	1.028	6.6	8.2	54.7
168	SC	1.030	6.8	7.8	59.5
169	SC	1.031	6.7	8.1	53.7
170	SC	1.037	6.6	5.5	32.3
171	SC	1.030	6.7	8.2	56.7
172	SC	1.023	6.4	10.3	74.0
173	SC	1.034	6.7	7.3	52.4
174	LC	1.054	5.8	3.8	26.8
175	SC	1.046	6.1	4.9	33.2
Mean	-	1.0377	6.46	6.90	47.65
SD	-	0.0130	0.33	2.03	15.30
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
16	SC	1.032	6.0	10.3	57.3
17	SC	1.031	6.3	6.6	40.9
18	SC	1.031	6.8	8.0	50.9
19	LC	1.042	6.2	5.7	36.1
20	SC	1.032	6.2	9.1	55.4
21	SC	1.038	6.3	7.0	44.0
22	SC	1.036	6.1	6.5	42.2
23	SC	1.039	6.1	4.3	26.6
24	SC	1.040	6.0	6.9	40.5
25	SC	1.028	6.6	10.3	61.7
Mean	-	1.0349	6.26	7.47	45.54
SD	-	0.0047	0.26	1.95	10.71
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
46	SC	1.029	6.4	3.6	23.1
47	SC	1.026	6.9	11.2	72.0
48	SC	1.025	6.3	12.0	71.0
49	LC	1.045	6.5	4.4	29.4
50	SC	1.033	6.4	8.0	51.2
51	SC	1.032	6.5	10.1	71.4
52	SC	1.028	6.7	10.9	70.4
53	LC	1.049	6.2	4.9	33.9
54	SC	1.040	6.0	6.3	42.2
55	LC	1.084	6.0	3.1	20.8
Mean	-	1.0391	6.39	7.45	48.55
SD	-	0.0177	0.28	3.41	21.35
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
76	SC	1.028	6.3	10.2	64.2
77	LC	1.060	6.2	4.7	30.2
78	LC	1.040	6.1	4.7	32.0
79	SC	1.035	6.1	9.8	52.6
80	SC	1.033	6.4	6.3	45.0
81	SC	1.034	6.5	7.5	47.9
82	SC	1.042	6.1	6.4	34.4
83	SC	1.034	6.6	7.2	47.2
84	SC	1.034	6.3	8.4	54.5
85	LC	1.068	6.1	2.8	18.2
Mean	-	1.0408	6.27	6.80	42.62
SD	-	0.0129	0.18	2.33	13.71
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
106	SC	1.043	6.5	6.1	36.0
107	LC	1.096	5.8	2.5	15.1
108	LC	1.046	6.3	5.0	31.7
109	SC	1.034	6.5	10.8	54.6
110	SC	1.039	6.3	6.2	37.2
111	SC	1.041	6.3	7.4	41.8
112	SC	1.068	6.0	4.7	31.2
113	SC	1.046	5.7	6.3	34.8
114	LC	1.070	5.9	3.7	24.0
115	SC	1.072	6.2	2.7	16.8
Mean	-	1.0555	6.15	5.54	32.31
SD	-	0.0199	0.28	2.45	11.72
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
136	SC	1.044	5.9	6.7	38.3
137	LC	1.070	6.1	3.3	21.8
138	LC	1.078	6.2	2.5	17.3
139	SC	1.032	6.4	8.5	52.4
140	SC	1.033	6.5	8.6	58.5
141	SC	1.044	6.4	6.7	40.5
142	SC	1.049	6.1	4.3	28.7
143	SC	1.033	6.3	8.8	52.4
144	SC	1.042	6.2	6.6	39.1
145	SC	1.039	6.6	6.4	36.5
Mean	-	1.0464	6.27	6.24	38.55
SD	-	0.0157	0.21	2.22	13.43
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
196	LC	1.036	6.2	7.5	41.6
197	LC	1.046	6.6	5.4	37.6
198	SC	1.040	6.4	2.7	18.8
199	SC	1.040	6.0	6.0	42.8
200	LC	1.043	6.2	5.9	33.3
201	SC	1.038	6.0	4.4	29.1
202	SC	1.025	6.4	9.6	66.9
203	SC	1.027	6.4	9.6	60.5
204	LC	1.045	6.3	5.6	32.7
205	LC	1.060	6.1	3.1	20.1
Mean	-	1.0400	6.26	5.98	38.35
SD	-	0.0099	0.20	2.37	15.62
N	-	10	10	10	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
176	SC	1.054	5.8	3.6	21.5
177	SC	1.039	6.2	5.1	28.8
178	LC	1.038	6.2	5.7	35.3
179	SC	1.040	5.9	5.8	33.6
180	SC	1.032	6.8	7.4	34.3
Mean	-	1.0406	6.18	5.52	30.70
SD	-	0.0081	0.39	1.37	5.74
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
26	SC	1.096	5.6	2.5	14.3
27	SC	1.025	6.4	10.2	47.6
28	SC	1.026	6.2	12.5	56.1
29	SC	1.029	6.4	8.5	45.3
30	SC	1.066	5.7	3.0	15.8
Mean	-	1.0484	6.06	7.34	35.81
SD	-	0.0316	0.38	4.43	19.38
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
56	LC	1.070	5.5	2.8	15.0
57	LC	1.036	6.4	3.5	19.4
58	SC	1.027	6.9	11.2	53.4
59	SC	1.045	6.1	5.9	29.2
60	SC	1.074	5.9	4.1	22.5
Mean	-	1.0504	6.16	5.50	27.90
SD	-	0.0208	0.53	3.39	15.15
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
86	SC	1.032	6.2	7.6	43.7
87	SC	1.047	6.4	5.5	28.2
88	SC	1.037	6.3	4.5	22.0
89	SC	1.050	6.2	4.8	26.6
90	SC	1.039	6.1	3.4	20.0
Mean	-	1.0410	6.24	5.16	28.12
SD	-	0.0074	0.11	1.56	9.35
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
116	SC	1.032	6.4	8.7	44.7
117	SC	1.043	5.9	4.1	21.7
118	LC	1.090	6.3	2.1	10.3
119	LC	1.072	5.9	3.2	16.5
120	SC	1.034	6.8	7.3	39.9
Mean	-	1.0542	6.26	5.08	26.63
SD	-	0.0256	0.38	2.80	14.99
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
146	SC	1.060	6.2	2.4	13.8
147	SC	1.070	6.1	3.0	16.3
148	SC	1.032	6.6	7.0	38.1
149	SC	1.045	6.8	4.0	19.5
150	SC	1.030	6.7	10.5	53.5
Mean	-	1.0474	6.48	5.38	28.22
SD	-	0.0174	0.31	3.36	17.07
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis				
	Colour	Specific Gravity (g/mL)	pH	Urine Volume -absolute- (mL/animal/ 16 h)	Urine Volume - relative - (mL/kg b.w./24 h)
206	SC	1.070	5.9	3.5	20.7
207	SC	1.035	6.2	5.5	30.1
208	SC	1.040	6.7	4.0	25.1
209	SC	1.036	6.4	6.4	35.4
210	SC	1.035	6.2	7.0	35.5
Mean	-	1.0432	6.28	5.28	29.37
SD	-	0.0151	0.29	1.51	6.47
N	-	5	5	5	5

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
166	+	0	0	0	0	0
167	0	0	0	0	0	0
168	+	0	0	0	0	0
169	0	0	0	0	0	0
170	0	0	0	0	0	0
171	++	0	0	0	0	0
172	++	0	0	0	0	0
173	+	0	0	0	0	0
174	+	0	0	0	0	0
175	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
16	0	0	0	0	0	0
17	+++	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	+	0	0	0	0	0
21	0	0	0	0	0	0
22	0	0	0	0	0	0
23	0	0	+	0	0	0
24	+++	+	0	0	0	0
25	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
46	+	0	0	0	0	0
47	0	0	0	0	0	0
48	+	0	0	0	0	0
49	0	0	++	0	0	0
50	0	0	0	0	0	0
51	0	0	0	0	0	0
52	0	0	0	0	0	0
53	0	0	0	0	0	0
54	+++	0	0	0	0	0
55	++	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
76	+	0	0	0	0	0
77	+	0	+	+	0	0
78	0	0	0	0	0	0
79	0	0	0	+	0	0
80	++	0	0	0	0	0
81	+	0	++	0	0	0
82	0	0	0	0	0	0
83	+	0	0	0	0	0
84	++	0	0	0	0	0
85	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
106	0	0	0	0	0	0
107	0	0	0	0	0	0
108	0	0	0	0	0	0
109	0	0	0	0	0	0
110	0	0	+	0	0	0
111	+	0	0	0	0	0
112	+++	0	0	0	0	0
113	+	0	0	0	0	0
114	0	0	0	0	0	0
115	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
136	0	0	0	0	0	0
137	0	0	++	0	0	0
138	0	0	+	0	0	0
139	+	0	0	0	0	0
140	++	0	0	0	0	0
141	0	0	+	0	0	0
142	+	0	0	0	0	0
143	++	0	0	0	0	0
144	+++	0	0	0	0	0
145	+	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
196	++	0	0	0	0	0
197	0	0	++	0	0	0
198	++	0	0	0	0	0
199	+	0	0	0	0	0
200	+	0	+	0	0	0
201	+	0	0	0	0	0
202	+	0	0	0	0	0
203	++	0	0	0	0	0
204	++	0	+	0	0	0
205	+	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
176	0	0	0	0	0	0
177	0	0	0	0	0	0
178	0	0	0	0	0	0
179	0	0	0	0	0	0
180	0	0	++	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
26	0	0	+++	0	0	0
27	0	0	0	0	0	0
28	+	0	0	0	0	0
29	+	0	0	0	0	0
30	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
56	0	0	0	0	0	0
57	0	0	++	0	0	0
58	0	0	0	0	0	0
59	0	0	0	0	0	0
60	0	0	0	+	0	0

FDA-CBER-2021-5683-0766956

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
86	0	0	0	0	0	0
87	0	0	+++	0	0	0
88	0	0	0	0	0	0
89	0	0	0	0	0	0
90	0	0	0	0	0	0

FDA-CBER-2021-5683-0766957

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
116	0	0	0	+	0	0
117	0	0	0	0	0	0
118	0	0	+	0	0	0
119	0	0	0	+	0	0
120	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
146	0	0	0	+	0	0
147	0	0	0	0	0	0
148	0	0	0	0	0	0
149	0	0	+	+	0	0
150	0	0	+	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis					
	Leucocytes	Erythrocytes	Crystalluria	Epithelial cells	Organisms	Further constituents
206	0	0	0	0	0	0
207	0	0	0	0	0	0
208	0	0	++	0	0	0
209	0	0	0	0	0	0
210	0	0	0	0	0	0

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
166	neg	0.3	normal	neg	normal	neg	neg
167	pos	0.3	normal	neg	normal	neg	neg
168	pos	0.3	normal	neg	normal	neg	neg
169	pos	0.3	normal	neg	normal	neg	neg
170	pos	0.3	normal	neg	normal	neg	neg
171	pos	0.3	normal	neg	normal	neg	neg
172	pos	0.3	normal	neg	normal	neg	10
173	pos	1.0	normal	neg	normal	neg	neg
174	neg	0.3	normal	neg	normal	neg	neg
175	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
16	pos	neg	normal	neg	normal	neg	neg
17	neg	0.3	normal	neg	normal	neg	10
18	pos	neg	normal	neg	normal	neg	neg
19	neg	0.3	normal	neg	normal	neg	neg
20	pos	neg	normal	neg	normal	neg	neg
21	neg	0.3	normal	neg	normal	neg	neg
22	neg	0.3	normal	neg	normal	neg	neg
23	neg	neg	normal	neg	normal	neg	neg
24	neg	neg	normal	neg	normal	neg	neg
25	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
46	pos	0.3	normal	neg	normal	neg	10
47	pos	neg	normal	neg	normal	neg	10
48	pos	neg	normal	neg	normal	neg	25
49	pos	0.3	normal	neg	normal	neg	25
50	pos	0.3	normal	neg	normal	neg	neg
51	pos	0.3	normal	neg	normal	neg	neg
52	pos	neg	normal	neg	normal	neg	neg
53	neg	0.3	normal	neg	normal	neg	neg
54	pos	0.3	normal	neg	normal	neg	neg
55	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
76	pos	neg	normal	neg	normal	neg	neg
77	neg	0.3	normal	neg	normal	neg	neg
78	neg	0.3	normal	neg	normal	neg	neg
79	pos	neg	normal	neg	normal	neg	neg
80	pos	neg	normal	neg	normal	neg	neg
81	pos	neg	normal	neg	normal	neg	neg
82	neg	0.3	normal	neg	normal	neg	neg
83	pos	neg	normal	neg	normal	neg	neg
84	pos	neg	normal	neg	normal	neg	neg
85	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
106	pos	0.3	normal	neg	normal	neg	neg
107	neg	0.3	normal	neg	normal	neg	neg
108	pos	0.3	normal	neg	normal	neg	neg
109	pos	0.3	normal	neg	normal	neg	neg
110	pos	0.3	normal	neg	normal	neg	neg
111	pos	0.3	normal	neg	normal	neg	neg
112	neg	0.3	normal	neg	normal	neg	25
113	neg	0.3	normal	neg	normal	neg	neg
114	neg	0.3	normal	neg	normal	neg	neg
115	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
136	neg	0.3	normal	neg	normal	neg	neg
137	neg	0.3	normal	neg	normal	neg	10
138	neg	0.3	normal	neg	normal	neg	neg
139	pos	0.3	normal	neg	normal	neg	10
140	pos	0.3	normal	neg	normal	neg	10
141	pos	0.3	normal	neg	normal	neg	neg
142	neg	0.3	normal	neg	normal	neg	neg
143	pos	0.3	normal	neg	normal	neg	neg
144	pos	0.3	normal	neg	normal	neg	neg
145	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
196	pos	0.3	normal	neg	normal	neg	neg
197	pos	0.3	normal	neg	normal	neg	neg
198	pos	0.3	normal	neg	normal	neg	neg
199	pos	0.3	normal	neg	normal	neg	neg
200	pos	0.3	normal	neg	normal	neg	neg
201	pos	0.3	normal	neg	normal	neg	neg
202	pos	0.3	normal	neg	normal	neg	neg
203	pos	0.3	normal	neg	normal	neg	neg
204	pos	0.3	normal	neg	normal	neg	neg
205	neg	0.3	normal	neg	normal	neg	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
176	neg	0.3	normal	neg	normal	neg	neg
177	neg	0.3	normal	neg	normal	neg	neg
178	pos	0.3	normal	neg	normal	neg	10
179	neg	0.3	normal	neg	normal	neg	neg
180	pos	0.3	normal	neg	normal	neg	10

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
26	neg	1.0	normal	neg	normal	neg	neg
27	neg	neg	normal	neg	normal	neg	neg
28	pos	neg	normal	neg	normal	neg	neg
29	neg	neg	normal	neg	normal	neg	neg
30	neg	1.0	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
56	neg	0.3	normal	neg	normal	neg	neg
57	neg	1.0	normal	neg	normal	neg	neg
58	neg	neg	normal	neg	normal	neg	neg
59	neg	0.3	normal	neg	normal	neg	neg
60	neg	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
86	neg	neg	normal	neg	normal	neg	neg
87	neg	0.3	normal	neg	normal	neg	neg
88	pos	0.3	normal	neg	normal	neg	neg
89	neg	0.3	normal	neg	normal	neg	neg
90	pos	0.3	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
116	pos	neg	normal	neg	normal	neg	neg
117	neg	neg	normal	neg	normal	neg	neg
118	neg	1.0	normal	neg	normal	neg	neg
119	neg	neg	normal	neg	normal	neg	neg
120	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
146	neg	0.3	normal	neg	normal	neg	neg
147	neg	0.3	normal	neg	normal	neg	neg
148	pos	neg	normal	neg	normal	neg	neg
149	neg	0.3	normal	neg	normal	neg	neg
150	pos	neg	normal	neg	normal	neg	neg

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TABLE 10-2 Urinalysis - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Urinalysis						
	Nitrite	Protein (g/L)	Glucose (mmol/L)	Ketones	Urobili-nogen (µmol/L)	Bilirubin	Haemoglobin (ery/µL)
206	neg	0.3	normal	neg	normal	neg	neg
207	pos	0.3	normal	neg	normal	neg	neg
208	neg	0.3	normal	neg	normal	neg	10
209	pos	0.3	normal	neg	normal	neg	neg
210	neg	0.3	normal	neg	normal	neg	neg

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Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins

TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 1: Control							
(1)	MS	0	0	0	0	–	–
(2)	MS	0	0	0	0	–	–
(3)	MS	0	0	0	0	–	–
(4)	MS	0	0	0	0	–	–
(5)	MS	0	0	0	0	–	–
(6)	MS	0	0	0	0	–	–
(7)	MS	0	0	0	0	–	–
(8)	MS	0	0	0	0	–	–
(9)	MS	0	0	0	0	–	–
(10)	MS	0	0	0	0	–	–
(11)	RP	0	0	0	0	0	0
(12)	RP	0	0	0	0	0	0
(13)	RP	0	0	0	0	0	0
(14)	RP	0	0	0	0	0	0
(15)	RP	0	0	0	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.							
(31)	MS	0	0	0	0	–	–
(32)	MS	0	0	0	0	–	–
(33)	MS	0	0	0	0	–	–
(34)	MS	0	0	0	0	–	–
(35)	MS	0	0	0	0	–	–
(36)	MS	0	0	0	0	–	–
(37)	MS	0	0	0	0	–	–
(38)	MS	0	0	0	0	–	–
(39)	MS	0	0	0	0	–	–
(40)	MS	0	0	0	0	–	–
(41)	RP	0	0	0	0	0	0
(42)	RP	0	0	0	0	0	0
(43)	RP	0	0	0	0	0	0
(44)	RP	0	0	0	0	0	0
(45)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins

TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
			Male animals				
Group 3: 10 µg BNT162a1/animal, i.m.							
(61)	MS	0	0	0	0	–	–
(62)	MS	0	0	0	0	–	–
(63)	MS	0	0	0	0	–	–
(64)	MS	0	0	0	0	–	–
(65)	MS	0	0	0	0	–	–
(66)	MS	0	0	0	0	–	–
(67)	MS	0	0	0	0	–	–
(68)	MS	0	0	0	0	–	–
(69)	MS	0	0	0	0	–	–
(70)	MS	0	0	0	0	–	–
(71)	RP	0	0	0	0	0	0
(72)	RP	0	0	0	0	0	0
(73)	RP	0	0	0	0	0	0
(74)	RP	0	0	0	0	0	0
(75)	RP	0	0	0	0	0	0
Group 4: 30 µg BNT162b1/animal, i.m.							
(91)	MS	0	0	0	0	–	–
(92)	MS	0	0	0	0	–	–
(93)	MS	0	0	0	0	–	–
(94)	MS	0	0	0	0	–	–
(95)	MS	0	0	0	0	–	–
(96)	MS	0	0	0	0	–	–
(97)	MS	0	0	0	0	–	–
(98)	MS	0	0	0	0	–	–
(99)	MS	0	0	0	0	–	–
(100)	MS	0	0	0	0	–	–
(101)	RP	0	0	0	0	0	0
(102)	RP	0	0	0	0	0	0
(103)	RP	0	0	0	0	0	0
(104)	RP	0	0	0	0	0	0
(105)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins

TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 5: 100 µg BNT162b1/animal, i.m.							
(121)	MS	0	0	0	0	–	–
(122)	MS	0	0	0	0	–	–
(123)	MS	0	0	0	0	–	–
(124)	MS	0	0	0	0	–	–
(125)	MS	0	0	0	0	–	–
(126)	MS	0	0	0	0	–	–
(127)	MS	0	0	0	0	–	–
(128)	MS	0	0	0	0	–	–
(129)	MS	0	0	0	0	–	–
(130)	MS	0	0	0	0	–	–
(131)	RP	0	0	0	0	0	0
(132)	RP	0	0	0	0	0	0
(133)	RP	0	0	0	0	0	0
(134)	RP	0	0	0	0	0	0
(135)	RP	0	0	0	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.							
(151)	MS	0	0	0	0	–	–
(152)	MS	0	0	0	0	–	–
(153)	MS	0	0	0	0	–	–
(154)	MS	0	0	0	0	–	–
(155)	MS	0	0	0	0	–	–
(156)	MS	0	0	0	0	–	–
(157)	MS	0	0	0	0	–	–
(158)	MS	0	0	0	0	–	–
(159)	MS	0	0	0	0	–	–
(160)	MS	0	0	0	0	–	–
(161)	RP	0	0	0	0	0	0
(162)	RP	0	0	0	0	0	0
(163)	RP	0	0	0	0	0	0
(164)	RP	0	0	0	0	0	0
(165)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Male animals					
Group 7: 100 µg BNT162b2/animal, i.m.							
(181)	MS	0	0	0	0	–	–
(182)	MS	0	0	0	0	–	–
(183)	MS	0	0	0	0	–	–
(184)	MS	0	0	0	0	–	–
(185)	MS	0	0	0	0	–	–
(186)	MS	0	0	0	0	–	–
(187)	MS	0	0	0	0	–	–
(188)	MS	0	0	0	0	–	–
(189)	MS	0	0	0	0	–	–
(190)	MS	0	0	0	0	–	–
(191)	RP	0	0	0	0	0	0
(192)	RP	0	0	0	0	0	0
(193)	RP	0	0	0	0	0	0
(194)	RP	0	0	0	0	0	0
(195)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 1: Control							
(16)	MS	0	0	0	0	–	–
(17)	MS	0	0	0	0	–	–
(18)	MS	0	0	0	0	–	–
(19)	MS	0	0	0	0	–	–
(20)	MS	0	0	0	0	–	–
(21)	MS	0	0	0	0	–	–
(22)	MS	0	0	0	0	–	–
(23)	MS	0	0	0	0	–	–
(24)	MS	0	0	0	0	–	–
(25)	MS	0	0	0	0	–	–
(26)	RP	0	0	0	0	0	0
(27)	RP	0	0	0	0	0	0
(28)	RP	0	0	0	0	0	0
(29)	RP	0	0	0	0	0	0
(30)	RP	0	0	0	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.							
(46)	MS	0	0	0	0	–	–
(47)	MS	0	0	0	0	–	–
(48)	MS	0	0	0	0	–	–
(49)	MS	0	0	0	0	–	–
(50)	MS	0	0	0	0	–	–
(51)	MS	0	0	0	0	–	–
(52)	MS	0	0	0	0	–	–
(53)	MS	0	0	0	0	–	–
(54)	MS	0	0	0	0	–	–
(55)	MS	0	0	0	0	–	–
(56)	RP	0	0	0	0	0	0
(57)	RP	0	0	0	0	0	0
(58)	RP	0	0	0	0	0	0
(59)	RP	0	0	0	0	0	0
(60)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 3: 10 µg BNT162a1/animal, i.m.							
(76)	MS	0	0	0	0	–	–
(77)	MS	0	0	0	0	–	–
(78)	MS	0	0	0	0	–	–
(79)	MS	0	0	0	0	–	–
(80)	MS	0	0	0	0	–	–
(81)	MS	0	0	0	0	–	–
(82)	MS	0	0	0	0	–	–
(83)	MS	0	0	0	0	–	–
(84)	MS	0	0	0	0	–	–
(85)	MS	0	0	0	0	–	–
(86)	RP	0	0	0	0	0	0
(87)	RP	0	0	0	0	0	0
(88)	RP	0	0	0	0	0	0
(89)	RP	0	0	0	0	0	0
(90)	RP	0	0	0	0	0	0
Group 4: 30 µg BNT162b1/animal, i.m.							
(106)	MS	0	0	0	0	–	–
(107)	MS	0	0	0	0	–	–
(108)	MS	0	0	0	0	–	–
(109)	MS	0	0	0	0	–	–
(110)	MS	0	0	0	0	–	–
(111)	MS	0	0	0	0	–	–
(112)	MS	0	0	0	0	–	–
(113)	MS	0	0	0	0	–	–
(114)	MS	0	0	0	0	–	–
(115)	MS	0	0	0	0	–	–
(116)	RP	0	0	0	0	0	0
(117)	RP	0	0	0	0	0	0
(118)	RP	0	0	0	0	0	0
(119)	RP	0	0	0	0	0	0
(120)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 5: 100 µg BNT162b1/animal, i.m.							
(136)	MS	0	0	0	0	–	–
(137)	MS	0	0	0	0	–	–
(138)	MS	0	0	0	0	–	–
(139)	MS	0	0	0	0	–	–
(140)	MS	0	0	0	0	–	–
(141)	MS	0	0	0	0	–	–
(142)	MS	0	0	0	0	–	–
(143)	MS	0	0	0	0	–	–
(144)	MS	0	0	0	0	–	–
(145)	MS	0	0	0	0	–	–
(146)	RP	0	0	0	0	0	0
(147)	RP	0	0	0	0	0	0
(148)	RP	0	0	0	0	0	0
(149)	RP	0	0	0	0	0	0
(150)	RP	0	0	0	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.							
(166)	MS	0	0	0	0	–	–
(167)	MS	0	0	0	0	–	–
(168)	MS	0	0	0	0	–	–
(169)	MS	0	0	0	0	–	–
(170)	MS	0	0	0	0	–	–
(171)	MS	0	0	0	0	–	–
(172)	MS	0	0	0	0	–	–
(173)	MS	0	0	0	0	–	–
(174)	MS	0	0	0	0	–	–
(175)	MS	0	0	0	0	–	–
(176)	RP	0	0	0	0	0	0
(177)	RP	0	0	0	0	0	0
(178)	RP	0	0	0	0	0	0
(179)	RP	0	0	0	0	0	0
(180)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 11 Ophthalmological Examination Rat

Animal no.	Main Study / Recovery period	Eye# Predose left	Predose right	End of MS left	End of MS right	End of RP left	End of RP right
		Female animals					
Group 7: 100 µg BNT162b2/animal, i.m.							
(196)	MS	0	0	0	0	–	–
(197)	MS	0	0	0	0	–	–
(198)	MS	0	0	0	0	–	–
(199)	MS	0	0	0	0	–	–
(200)	MS	0	0	0	0	–	–
(201)	MS	0	0	0	0	–	–
(202)	MS	0	0	0	0	–	–
(203)	MS	0	0	0	0	–	–
(204)	MS	0	0	0	0	–	–
(205)	MS	0	0	0	0	–	–
(206)	RP	0	0	0	0	0	0
(207)	RP	0	0	0	0	0	0
(208)	RP	0	0	0	0	0	0
(209)	RP	0	0	0	0	0	0
(210)	RP	0	0	0	0	0	0

0 = no pathological findings
= includes: adnexa oculi (i.e. lids, lacrimal apparatus), conjunctiva, cornea, anterior chamber, lens, vitreous body, fundus (retina, optic disc)
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 1: Control				
(1)	MS	0	0	–
(2)	MS	0	0	–
(3)	MS	0	0	–
(4)	MS	0	0	–
(5)	MS	0	0	–
(6)	MS	0	0	–
(7)	MS	0	0	–
(8)	MS	0	0	–
(9)	MS	0	0	–
(10)	MS	0	0	–
(11)	RP	0	0	0
(12)	RP	0	0	0
(13)	RP	0	0	0
(14)	RP	0	0	0
(15)	RP	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.				
(31)	MS	0	0	–
(32)	MS	0	0	–
(33)	MS	0	0	–
(34)	MS	0	0	–
(35)	MS	0	0	–
(36)	MS	0	0	–
(37)	MS	0	0	–
(38)	MS	0	0	–
(39)	MS	0	0	–
(40)	MS	0	0	–
(41)	RP	0	0	0
(42)	RP	0	0	0
(43)	RP	0	0	0
(44)	RP	0	0	0
(45)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 3: 10 μg BNT162a1/animal, i.m.				
(61)	MS	0	0	–
(62)	MS	0	0	–
(63)	MS	0	0	–
(64)	MS	0	0	–
(65)	MS	0	0	–
(66)	MS	0	0	–
(67)	MS	0	0	–
(68)	MS	0	0	–
(69)	MS	0	0	–
(70)	MS	0	0	–
(71)	RP	0	0	0
(72)	RP	0	0	0
(73)	RP	0	0	0
(74)	RP	0	0	0
(75)	RP	0	0	0
Group 4: 30 μg BNT162b1/animal, i.m.				
(91)	MS	0	0	–
(92)	MS	0	0	–
(93)	MS	0	0	–
(94)	MS	0	0	–
(95)	MS	0	0	–
(96)	MS	0	0	–
(97)	MS	0	0	–
(98)	MS	0	0	–
(99)	MS	0	0	–
(100)	MS	0	0	–
(101)	RP	0	0	0
(102)	RP	0	0	0
(103)	RP	0	0	0
(104)	RP	0	0	0
(105)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 5: 100 µg BNT162b1/animal, i.m.				
(121)	MS	0	0	–
(122)	MS	0	0	–
(123)	MS	0	0	–
(124)	MS	0	0	–
(125)	MS	0	0	–
(126)	MS	0	0	–
(127)	MS	0	0	–
(128)	MS	0	0	–
(129)	MS	0	0	–
(130)	MS	0	0	–
(131)	RP	0	0	0
(132)	RP	0	0	0
(133)	RP	0	0	0
(134)	RP	0	0	0
(135)	RP	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.				
(151)	MS	0	0	–
(152)	MS	0	0	–
(153)	MS	0	0	–
(154)	MS	0	0	–
(155)	MS	0	0	–
(156)	MS	0	0	–
(157)	MS	0	0	–
(158)	MS	0	0	–
(159)	MS	0	0	–
(160)	MS	0	0	–
(161)	RP	0	0	0
(162)	RP	0	0	0
(163)	RP	0	0	0
(164)	RP	0	0	0
(165)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Male animals		
Group 7: 100 µg BNT162b2/animal, i.m.				
(181)	MS	0	0	–
(182)	MS	0	0	–
(183)	MS	0	0	–
(184)	MS	0	0	–
(185)	MS	0	0	–
(186)	MS	0	0	–
(187)	MS	0	0	–
(188)	MS	0	0	–
(189)	MS	0	0	–
(190)	MS	0	0	–
(191)	RP	0	0	0
(192)	RP	0	0	0
(193)	RP	0	0	0
(194)	RP	0	0	0
(195)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 1: Control				
(16)	MS	0	0	–
(17)	MS	0	0	–
(18)	MS	0	0	–
(19)	MS	0	0	–
(20)	MS	0	0	–
(21)	MS	0	0	–
(22)	MS	0	0	–
(23)	MS	0	0	–
(24)	MS	0	0	–
(25)	MS	0	0	–
(26)	RP	0	0	0
(27)	RP	0	0	0
(28)	RP	0	0	0
(29)	RP	0	0	0
(30)	RP	0	0	0
Group 2: 30 µg BNT162a1/animal, i.m.				
(46)	MS	0	0	–
(47)	MS	0	0	–
(48)	MS	0	0	–
(49)	MS	0	0	–
(50)	MS	0	0	–
(51)	MS	0	0	–
(52)	MS	0	0	–
(53)	MS	0	0	–
(54)	MS	0	0	–
(55)	MS	0	0	–
(56)	RP	0	0	0
(57)	RP	0	0	0
(58)	RP	0	0	0
(59)	RP	0	0	0
(60)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 3: 10 μg BNT162a1/animal, i.m.				
(76)	MS	0	0	–
(77)	MS	0	0	–
(78)	MS	0	0	–
(79)	MS	0	0	–
(80)	MS	0	0	–
(81)	MS	0	0	–
(82)	MS	0	0	–
(83)	MS	0	0	–
(84)	MS	0	0	–
(85)	MS	0	0	–
(86)	RP	0	0	0
(87)	RP	0	0	0
(88)	RP	0	0	0
(89)	RP	0	0	0
(90)	RP	0	0	0
Group 4: 30 μg BNT162b1/animal, i.m.				
(106)	MS	0	0	–
(107)	MS	0	0	–
(108)	MS	0	0	–
(109)	MS	0	0	–
(110)	MS	0	0	–
(111)	MS	0	0	–
(112)	MS	0	0	–
(113)	MS	0	0	–
(114)	MS	0	0	–
(115)	MS	0	0	–
(116)	RP	0	0	0
(117)	RP	0	0	0
(118)	RP	0	0	0
(119)	RP	0	0	0
(120)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms
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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 5: 100 µg BNT162b1/animal, i.m.				
(136)	MS	0	0	–
(137)	MS	0	0	–
(138)	MS	0	0	–
(139)	MS	0	0	–
(140)	MS	0	0	–
(141)	MS	0	0	–
(142)	MS	0	0	–
(143)	MS	0	0	–
(144)	MS	0	0	–
(145)	MS	0	0	–
(146)	RP	0	0	0
(147)	RP	0	0	0
(148)	RP	0	0	0
(149)	RP	0	0	0
(150)	RP	0	0	0
Group 6: 30 µg BNT162c1/animal, i.m.				
(166)	MS	0	0	
(167)	MS	0	0	–
(168)	MS	0	0	–
(169)	MS	0	0	–
(170)	MS	0	0	–
(171)	MS	0	0	–
(172)	MS	0	0	–
(173)	MS	0	0	–
(174)	MS	0	0	–
(175)	MS	0	0	–
(176)	RP	0	0	–
(177)	RP	0	0	0
(178)	RP	0	0	0
(179)	RP	0	0	0
(180)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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TABLE 12 Auditory Examination Rat

Animal no.	Main Study / Recovery period	Hearing		
		Predose	End of MS	End of RP
		Female animals		
Group 7: 100 µg BNT162b2/animal, i.m.				
(196)	MS	0	0	–
(197)	MS	0	0	–
(198)	MS	0	0	–
(199)	MS	0	0	–
(200)	MS	0	0	–
(201)	MS	0	0	–
(202)	MS	0	0	–
(203)	MS	0	0	–
(204)	MS	0	0	–
(205)	MS	0	0	–
(206)	RP	0	0	0
(207)	RP	0	0	0
(208)	RP	0	0	0
(209)	RP	0	0	0
(210)	RP	0	0	0

0 = no pathological findings
MS = main study (treatment period)
RP = recovery period

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 1: Control			
Terminal sacrifice			
(1)	TS / TD 17	—	no pathological findings
(2)	TS / TD 17	—	no pathological findings
(3)	TS / TD 17	—	no pathological findings
(4)	TS / TD 17	—	no pathological findings
(5)	TS / TD 17	—	no pathological findings
(6)	TS / TD 17	—	no pathological findings
(7)	TS / TD 17	Lungs:	emphysematous
(8)	TS / TD 17	—	no pathological findings
(9)	TS / TD 17	Thymus:	reddened
(10)	TS / TD 17	—	no pathological findings
Recovery sacrifice			
(11)	RS / TD 38	—	no pathological findings
(12)	RS / TD 38	—	no pathological findings
(13)	RS / TD 38	—	no pathological findings
(14)	RS / TD 38	—	no pathological findings
(15)	RS / TD 38	Testis (right):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice

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TABLE 13 Three LNP-Formulated RNA Platforms Encoding for Viral Proteins
Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(31)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(32)	TS / TD 17	Injection site I:	indurated
(33)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged
		Prostate:	reduced in size
		Seminal vesicles:	reduced in size
		Adrenal glands:	enlarged
(34)	TS / TD 17	Injection site I:	muscles thickened, indurated
(35)	TS / TD 17	External observation:	injection site I indurated
		Injection site I:	indurated
(36)	TS / TD 17	External observation:	injection site I indurated, incrustation (diameter approx. 4 mm)
		Injection site I:	indurated
(37)	TS / TD 17	External observation:	injection site II incrusted
		Injection site I:	muscles thickened, indurated

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(38)	TS / TD 17	Injection site I:	indurated
(39)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(40)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
Recovery sacrifice			
(41)	RS / TD 38	—	no pathological findings
(42)	RS / TD 38	—	no pathological findings
(43)	RS / TD 38	—	no pathological findings
(44)	RS / TD 38	—	no pathological findings
(45)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(61)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(62)	TS / TD 17	—	no pathological findings
(63)	TS / TD 17	External observation:	injection site I thickened, skin incrusted
		Injection site I:	muscle indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(64)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Lymph node (iliac):	enlarged
(65)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(66)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(67)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscle indurated
(68)	TS / TD 17	Injection site I:	indurated
(69)	TS / TD 17	—	no pathological findings
(70)	TS / TD 17	Spleen:	enlarged
Recovery sacrifice			
(71)	RS / TD 38	—	no pathological findings
(72)	RS / TD 38	—	no pathological findings
(73)	RS / TD 38	—	no pathological findings
(74)	RS / TD 38	—	no pathological findings
(75)	RS / TD 38	—	no pathological findings

TD test day
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 4: 30 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(91)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(92)	TS / TD 17	Injection site I:	indurated
(93)	TS / TD 17	Lymph node (iliac):	enlarged
(94)	TS / TD 17	—	no pathological findings
(95)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(96)	TS / TD 17	Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged
(97)	TS / TD 17	—	no pathological findings
(98)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(99)	TS / TD 17	Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged
(100)	TS / TD 17	Injection site I:	muscle indurated, thickened

TD test day I: left
TS terminal sacrifice II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 4: 30 µg BNT162b1/animal, i.m.			
Recovery sacrifice			
(101)	RS / TD 38	—	no pathological findings
(102)	RS / TD 38	—	no pathological findings
(103)	RS / TD 38	Testis (right):	enlarged
(104)	RS / TD 38	—	no pathological findings
(105)	RS / TD 38	—	no pathological findings

TD test day
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(121)	TS / TD 17	Injection site I+II:	enlarged
		Lymph node (renal, left)	enlarged
		Spleen:	enlarged
(122)	TS / TD 17	—	no pathological findings
(123)	TS / TD 17	Injection site I+II:	muscle indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(124)	TS / TD 17	Injection site I+II:	thickened
		Lymph node (iliac):	enlarged
(125)	TS / TD 17	—	no pathological findings
(126)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(127)	TS / TD 17	External observation:	injection site I thickened
		Injection site I+II:	muscle indurated
		Adrenal glands:	enlarged
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(128)	TS / TD 17	Spleen:	enlarged
(129)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
(130)	TS / TD 17	Injection site I+II:	muscle indurated
		Spleen:	enlarged
		Adrenal glands:	enlarged
		Lymph node (iliac):	enlarged
Recovery sacrifice			
(131)	RS / TD 38	Lymph node (iliac):	enlarged
(132)	RS / TD 38	Lymph node (iliac):	enlarged
(133)	RS / TD 38	Lymph node (iliac):	enlarged
(134)	RS / TD 38	Lymph node (iliac):	enlarged
(135)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(151)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscles indurated
(152)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Spleen:	enlarged
(153)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
(154)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
		Spleen:	enlarged
(155)	TS / TD 10	Injection site I:	muscle indurated
		Spleen:	enlarged
(156)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(157)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
(158)	TS / TD 10	External observation:	injection site I thickened, incrusted
		Injection site I:	muscle indurated
(159)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
(160)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
		Spleen:	enlarged
Recovery sacrifice			
(161)	RS / TD 31	—	no pathological findings
(162)	RS / TD 31	—	no pathological findings
(163)	RS / TD 31	—	no pathological findings
(164)	RS / TD 31	—	no pathological findings
(165)	RS / TD 31	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 7: 100 µg BNT162b2/animal, i.m.			
Terminal sacrifice			
(181)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
(182)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
(183)	TS / TD 17	—	no pathological findings
(184)	TS / TD 17	External observation:	injection site I thickened
		Injection site I+II:	enlarged
		Lymph node (iliac):	enlarged
		Lymph node (renal):	enlarged
(185)	TS / TD 17	—	no pathological findings
(186)	TS / TD 17	—	no pathological findings
		Injection site I:	indurated
(187)	TS / TD 17	Lymph node (iliac):	enlarged
		Injection site I+II:	indurated
		Spleen:	enlarged
(188)	TS / TD 17	Injection site I+II:	thickened

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Males	
Group 7: 100 µg BNT162b2/animal, i.m.			
(189)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(190)		—	no pathological findings
Recovery sacrifice			
(191)	RS / TD 38	—	no pathological findings
(192)	RS / TD 38	—	no pathological findings
(193)	RS / TD 38	—	no pathological findings
(194)	RS / TD 38	—	no pathological findings
(195)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
RS recovery sacrifice
I: left
II: right

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TABLE 13 Three LNP-Formulated RNA Platforms Encoding for Viral Proteins Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 1: Control			
Terminal sacrifice			
(16)	TS / TD 17	—	no pathological findings
(17)	TS / TD 17	—	no pathological findings
(18)	TS / TD 17	—	no pathological findings
(19)	TS / TD 17	—	no pathological findings
(20)	TS / TD 17	—	no pathological findings
(21)	TS / TD 17	—	no pathological findings
(22)	TS / TD 17	—	no pathological findings
(23)	TS / TD 17	—	no pathological findings
(24)	TS / TD 17	—	no pathological findings
(25)	TS / TD 17	—	no pathological findings
Recovery sacrifice			
(26)	RS / TD 38	—	no pathological findings
(27)	RS / TD 38	—	no pathological findings
(28)	RS / TD 38	—	no pathological findings
(29)	RS / TD 38	—	no pathological findings
(30)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

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TABLE 13 Three LNP-Formulated RNA Platforms Encoding for Viral Proteins
Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(46)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Spleen:	enlarged
(47)	TS / TD 17	Injection site I:	indurated
(48)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
(49)	TS / TD 17	External observation:	injection site I incrusted
		Injection site I:	muscle thickened, indurated
(50)	TS / TD 17	Injection site I:	muscle thickened, indurated
(51)	TS / TD 17	Uterus:	dilated
		Injection site I:	indurated
(52)	TS / TD 17	Injection site I:	muscle thickened, indurated
		Spleen:	enlarged
(53)	TS / TD 17	External observation:	injection site I thickened, skin incrusted
		Injection site I:	muscles indurated
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 2: 30 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(54)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
		Spleen:	enlarged
(55)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscles indurated
Recovery sacrifice			
(56)	RS / TD 38	—	no pathological findings
(57)	RS / TD 38	—	no pathological findings
(58)	RS / TD 38	—	no pathological findings
(59)	RS / TD 38	—	no pathological findings
(60)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(76)	TS / TD 17	—	no pathological findings
(77)	TS / TD 17	—	no pathological findings
(78)	TS / TD 17	Injection site I:	indurated
(79)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
		Uterus:	dilated, filled with clear liquid
		Adrenal glands:	enlarged
(80)	TS / TD 17	Injection site I:	muscle indurated
(81)	TS / TD 17	Injection site I:	indurated
(82)	TS / TD 17	Injection site I:	indurated
		Uterus:	dilated, filled with clear liquid
(83)	TS / TD 17	Injection site I:	indurated
		Spleen:	enlarged
		Uterus:	dilated, filled with clear liquid
		Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 3: 10 µg BNT162a1/animal, i.m.			
Terminal sacrifice			
(84)	TS / TD 17	External observation:	injection site I enlarged
		Injection site 1:	enlarged
		Lymph node (iliac):	enlarged
(85)	TS / TD 17	Injection site 1:	thickened
		Lymph node (iliac):	enlarged
Recovery sacrifice			
(86)	RS / TD 38	—	no pathological findings
(87)	RS / TD 38	—	no pathological findings
(88)	RS / TD 38	—	no pathological findings
(89)	RS / TD 38	—	no pathological findings
(90)	RS / TD 38	—	no pathological findings

TD test day
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 4: 30 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(106)	TS / TD 17	Injection site I:	indurated
(107)	TS / TD 17	—	no pathological findings
(108)	TS / TD 17	Injection site I:	muscle indurated, thickened
(109)	TS / TD 17	Uterus:	dilated
		Lymph node (iliac):	enlarged
(110)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(111)	TS / TD 17	Spleen:	enlarged
(112)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(113)	TS / TD 17	Lymph node (iliac):	enlarged
(114)	TS / TD 17	Injection site I:	indurated
(115)	TS / TD 17	Injection site I:	indurated

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 4: 30 µg BNT162b1/animal, i.m.			
Recovery sacrifice			
(116)	RS / TD 38	Uterus:	dilated, filled with clear liquid
(117)	RS / TD 38	Lymph node (iliac):	enlarged
(118)	RS / TD 38	—	no pathological findings
(119)	RS / TD 38	—	no pathological findings
(120)	RS / TD 38	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice

I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(136)	TS / TD 17	Spleen:	enlarged
(137)	TS / TD 17	Injection site I:	muscles indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(138)	TS / TD 17	External observation:	injection site I+II thickened
		Injection site I+II:	muscles indurated
		Lymph node (iliac):	enlarged
(139)	TS / TD 17	Injection site I+II:	indurated
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(140)	TS / TD 17	Injection site I+II:	thickened
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(141)	TS / TD 17	Lymph node (iliac):	enlarged
		Spleen:	enlarged

TD test day
TS terminal sacrifice
I: left
II: right

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TABLE 13 Three LNP-Formulated RNA Platforms Encoding for Viral Proteins
Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 5: 100 µg BNT162b1/animal, i.m.			
Terminal sacrifice			
(142)	TS / TD 17	Injection site I+II:	thickened
		Sciatic nerve (left):	adhered to injection site I
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(143)	TS / TD 17	Injection site I:	indurated
		Lymph node (iliac):	enlarged
(144)	TS / TD 17	Lymph node (iliac):	enlarged
(145)	TS / TD 17	Spleen:	enlarged
Recovery sacrifice			
(146)	RS / TD 38	—	no pathological findings
(147)	RS / TD 38	Uterus:	dilated, filled with clear liquid
(148)	RS / TD 38	—	no pathological findings
(149)	RS / TD 38	Lymph node (iliac):	enlarged
(150)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
			Females
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(166)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	thickened
(167)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
(168)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Spleen:	enlarged
(169)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
		Lymph node (iliac):	enlarged
(170)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	indurated
(171)	TS / TD 10	Injection site I:	muscle indurated
(172)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 6: 30 µg BNT162c1/animal, i.m.			
Terminal sacrifice			
(173)	TS / TD 10	External observation:	injection site I thickened, incrusted
		Injection site I:	muscle indurated
(174)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
		Lymph node (iliac):	enlarged
(175)	TS / TD 10	External observation:	injection site I thickened
		Injection site I:	muscle indurated
Recovery sacrifice			
(176)	RS / TD 31	—	no pathological findings
(177)	RS / TD 31	—	no pathological findings
(178)	RS / TD 31	—	no pathological findings
(179)	RS / TD 31	—	no pathological findings
(180)	RS / TD 31	—	no pathological findings

TD test day
TS terminal sacrifice
RS recovery sacrifice
I: left
II: right

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TABLE 13 Three LNP-Formulated RNA Platforms Encoding for Viral Proteins Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 7: 100 µg BNT162b2/animal, i.m.			
Terminal sacrifice			
(196)	TS / TD 17	Injection site I:	thickened
		Spleen:	enlarged
(197)	TS / TD 17	External observation:	injection site I thickened
		Injection site I:	muscle jellied, adhered to sciatic nerve and bone
		Lymph node (iliac):	enlarged
		Spleen:	enlarged
(198)	TS / TD 17	Injection site I:	indurated
(199)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Uterus:	dilated, filled with clear liquid
		Lymph node (iliac):	enlarged
(200)	TS / TD 17	Lymph node (iliac):	enlarged
		Injection site I:	indurated
(201)	TS / TD 17	Injection site I+II:	indurated
		Sciatic nerve (left):	adhered to injection site I

TD test day
TS terminal sacrifice
I: left
II: right

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Three LNP-Formulated RNA Platforms Encoding for Viral Proteins

TABLE 13 Macroscopic *Post Mortem* Findings Rat

Animal no.	Day of sacrifice	Affected organs	Findings
		Females	
Group 7: 100 µg BNT162b2/animal, i.m.			
Terminal sacrifice			
(202)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(203)	TS / TD 17	Spleen:	enlarged
(204)	TS / TD 17	Injection site I+II:	indurated
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
(205)	TS / TD 17	Injection site I:	indurated
		Sciatic nerve (left):	adhered to injection site I
		Spleen:	enlarged
		Lymph node (iliac):	enlarged
Recovery sacrifice			
(206)	RS / TD 38	—	no pathological findings
(207)	RS / TD 38	Lymph node (iliac):	enlarged
(208)	RS / TD 38	—	no pathological findings
(209)	RS / TD 38	Lymph node (iliac):	enlarged
(210)	RS / TD 38	Lymph node (iliac):	enlarged

TD test day
TS terminal sacrifice
RS recovery sacrifice
I: left
II: right

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.1473	0.1434	7.245	1.690	1.730	6.458	6.565
	SD	0.0176	0.0158	0.371	0.241	0.280	0.417	0.693
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

FDA-CBER-2021-5683-0767017

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	4.037	4.984	4.949	40.65	6.285	0.0640	0.1218
	SD	0.589	0.334	0.296	1.58	0.588	0.0122	0.0457
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

FDA-CBER-2021-5683-0767018

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0371	2.8607	3.775	1.713	0.0405
	SD	0.0032	0.5571	0.508	0.389	0.0115
	N	10	10	10	10	10
		-	-	-	-	-

FDA-CBER-2021-5683-0767019

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a1]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a1]	Epididymis (right) (g/kg b.w.) [a1]	Testis (left) (g/kg b.w.) [a1]	Testis (right) (g/kg b.w.) [a]
Group 1: Control	Mean	0.1167	0.1081	6.141	1.401	1.284	5.511	5.447
	SD	0.0144	0.0149	0.207	0.233	0.114	0.448	0.421
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.1529**	0.1498**	7.195**	1.652	1.621**	6.421**	6.472**
	SD	0.0203	0.0235	0.473	0.116	0.176	0.411	0.388
	N	10	10	10	10	10	10	10
	%Diff	31.0	38.6	17.2	17.9	26.2	16.5	18.8
Group 3: 10 µg/ animal BNT162a1	Mean	0.1237	0.1261	6.061	1.759**	1.595**	5.717	5.690
	SD	0.0165	0.0176	0.447	0.256	0.244	0.446	0.348
	N	10	10	10	10	10	10	10
	%Diff	6.0	16.7	-1.3	25.5	24.2	3.7	4.5
Group 4: 30 µg/ animal BNT162b1	Mean	0.1383	0.1299	6.487	1.617	1.525*	5.901	5.840
	SD	0.0165	0.0258	0.304	0.151	0.146	0.369	0.426
	N	10	10	10	10	10	10	10
	%Diff	18.6	20.2	5.6	15.4	18.7	7.1	7.2

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0767020

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a]	Epididymis (right) (g/kg b.w.) [a]	Testis (left) (g/kg b.w.) [a]	Testis (right) (g/kg b.w.) [a]
Group 5:	Mean	0.1398	0.1383*	6.432	1.731*	1.754**	5.992	5.867
100 µg/	SD	0.0318	0.0266	0.445	0.193	0.285	0.722	0.587
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	19.8	28.0	4.7	23.6	36.5	8.7	7.7
Group 7:	Mean	0.1439*	0.1248	6.537	1.857**	1.720**	6.180*	6.090**
100 µg/	SD	0.0223	0.0372	0.518	0.359	0.302	0.471	0.367
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	23.4	15.5	6.4	32.5	33.9	12.1	11.8

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

FDA-CBER-2021-5683-0767021

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a1]	Kidney (right) (g/kg b.w.) [a1]	Liver (g/kg b.w.) [a1]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a2]
Group 1: Control	Mean	3.493	4.369	4.531	39.90	5.945	0.0644	0.1010
	SD	0.140	0.252	0.325	1.59	1.632	0.0326	0.0487
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.024**	4.819*	4.919	38.93	6.805**	0.0730	0.1428
	SD	0.551	0.481	0.556	3.31	0.799	0.0107	0.0618
	N	10	10	10	10	10	10	10
	%Diff	15.2	10.3	8.6	-2.4	14.5	13.3	41.4
Group 3: 10 µg/ animal BNT162a1	Mean	3.561	4.377	4.459	39.05	6.163	0.0579	0.1204
	SD	0.336	0.315	0.205	2.60	0.548	0.0130	0.0566
	N	10	10	10	10	10	10	10
	%Diff	1.9	0.2	-1.6	-2.1	3.7	-10.1	19.2
Group 4: 30 µg/ animal BNT162b1	Mean	3.623	4.644	4.690	38.73	5.903	0.0740	0.1097
	SD	0.331	0.296	0.275	2.50	0.511	0.0625	0.0620
	N	10	10	10	10	10	10	10
	%Diff	3.7	6.3	3.5	-2.9	-0.7	14.9	8.6

[a] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a1] - Anova & Dunnett: * = p ≤ 0.05
[a2] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767022

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	3.771	4.809*	4.745	42.65	6.199	0.0601	0.1463
100 µg/	SD	0.311	0.365	0.296	4.27	0.585	0.0228	0.0788
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	8.0	10.1	4.7	6.9	4.3	-6.7	44.8
Group 7:	Mean	3.799*	4.667	4.810	40.68	6.286	0.0529	0.1687
100 µg/	SD	0.336	0.404	0.442	1.95	0.689	0.0161	0.0948
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	8.8	6.8	6.1	2.0	5.7	-17.8	67.0

[a] - Anova & Dunnett: * = $p \leq 0.05$

FDA-CBER-2021-5683-0767023

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a1]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 1: Control	Mean	0.0391	2.8411	2.568	1.647	0.0402
	SD	0.0043	0.5188	0.378	0.294	0.0095
	N	10	10	10	10	10
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0454	2.9005	3.584**	1.695	0.0509*
	SD	0.0087	0.7572	0.377	0.297	0.0073
	N	10	10	10	10	10
	%Diff	16.0	2.1	39.6	2.9	26.5
Group 3: 10 µg/ animal BNT162a1	Mean	0.0398	2.6968	3.283**	1.618	0.0379
	SD	0.0064	0.6254	0.284	0.369	0.0094
	N	10	10	10	10	10
	%Diff	1.6	-5.1	27.8	-1.8	-5.9
Group 4: 30 µg/ animal BNT162b1	Mean	0.0415	2.7895	3.141**	1.548	0.0443
	SD	0.0066	0.5007	0.332	0.347	0.0071
	N	10	10	10	10	10
	%Diff	6.1	-1.8	22.3	-6.0	10.0

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0767024

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0384	2.5310	3.339**	1.405	0.0338
100 µg/	SD	0.0075	0.6737	0.383	0.264	0.0061
animal	N	10	9	10	10	10
BNT162b1	%Diff	-2.0	-10.9	30.0	-14.7	-16.1
Group 7:	Mean	0.0379	2.7095	3.508**	1.297*	0.0370
100 µg/	SD	0.0043	0.5848	0.268	0.651	0.0113
animal	N	10	10	10	10	10
BNT162b2	%Diff	-3.1	-4.6	36.6	-21.3	-8.0

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.1009	0.0995	5.544	1.777	1.874	5.170	5.584
	SD	0.0152	0.0138	0.546	0.185	0.156	0.381	1.038
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

FDA-CBER-2021-5683-0767026

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	3.483	4.223	4.365	35.79	6.070	0.0489	0.1111
	SD	0.365	0.309	0.490	2.13	1.026	0.0141	0.0366
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

FDA-CBER-2021-5683-0767027

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0349	2.7828	2.242	1.109	0.0399
	SD	0.0050	0.4167	0.258	0.143	0.0113
	N	5	5	5	5	5
		-	-	-	-	-

FDA-CBER-2021-5683-0767028

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a]	Epididymis (right) (g/kg b.w.) [a]	Testis (left) (g/kg b.w.) [a]	Testis (right) (g/kg b.w.) [a1]
Group 1: Control	Mean	0.0979	0.0988	5.356	1.847	1.709	5.426	5.980
	SD	0.0132	0.0144	0.278	0.212	0.160	0.607	1.749
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.1204*	0.1172	5.311	1.803	1.772	5.025	5.139
	SD	0.0116	0.0247	0.232	0.278	0.253	0.284	0.404
	N	5	5	5	5	5	5	4
	%Diff	23.0	18.7	-0.9	-2.4	3.7	-7.4	-14.1
Group 3: 10 µg/ animal BNT162a1	Mean	0.1078	0.1051	5.257	1.977	1.997	5.024	5.021
	SD	0.0080	0.0156	0.221	0.120	0.112	0.390	0.457
	N	5	5	5	5	5	5	5
	%Diff	10.0	6.4	-1.9	7.0	16.9	-7.4	-16.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.0878	0.0874	5.065	1.671	1.547	5.227	5.614
	SD	0.0084	0.0161	0.398	0.256	0.249	0.730	1.635
	N	5	5	5	5	5	5	5
	%Diff	-10.3	-11.5	-5.4	-9.5	-9.4	-3.7	-6.1

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0767029

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Epididymis (left) (g/kg b.w.) [a]	Epididymis (right) (g/kg b.w.) [a]	Testis (left) (g/kg b.w.) [a]	Testis (right) (g/kg b.w.) [a]
Group 5:	Mean	0.1022	0.1003	5.396	2.090	2.009	5.042	5.077
100 µg/	SD	0.0117	0.0036	0.293	0.217	0.134	0.460	0.500
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	4.3	1.6	0.7	13.2	17.6	-7.1	-15.1
Group 7:	Mean	0.0929	0.0972	5.337	1.882	1.869	5.229	5.235
100 µg/	SD	0.0136	0.0175	0.607	0.218	0.229	0.291	0.423
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	-5.2	-1.5	-0.4	1.9	9.4	-3.6	-12.5

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a1]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 1: Control	Mean	3.289	4.378	4.649	35.10	5.281	0.0500	0.0653
	SD	0.138	0.125	0.229	2.91	0.545	0.0145	0.0154
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	3.417	4.246	4.302	36.86	5.639	0.0544	0.0781
	SD	0.163	0.350	0.434	1.85	0.484	0.0389	0.0236
	N	5	5	5	5	5	5	5
	%Diff	3.9	-3.0	-7.5	5.0	6.8	8.8	19.5
Group 3: 10 µg/ animal BNT162a1	Mean	3.414	4.161	4.121	36.34	5.367	0.0550	0.1094
	SD	0.072	0.376	0.097	1.10	0.771	0.0145	0.0212
	N	5	5	5	5	5	5	5
	%Diff	3.8	-5.0	-11.4	3.5	1.6	9.9	67.5
Group 4: 30 µg/ animal BNT162b1	Mean	3.341	4.130	4.186	37.98	5.618	0.0418	0.0693
	SD	0.073	0.226	0.298	1.92	0.169	0.0112	0.0322
	N	5	5	5	5	5	5	5
	%Diff	1.6	-5.7	-10.0	8.2	6.4	-16.5	6.0

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767031

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights						
		Heart (g/kg b.w.) [a]	Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	3.364	4.092	4.312	35.73	5.226	0.0464	0.1217*
100 µg/	SD	0.216	0.373	0.462	1.33	0.606	0.0107	0.0290
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	2.3	-6.5	-7.3	1.8	-1.0	-7.3	86.3
Group 7:	Mean	3.486	4.073	4.247	34.46	5.905	0.0469	0.0966
100 µg/	SD	0.306	0.184	0.242	2.39	1.059	0.0071	0.0361
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	6.0	-7.0	-8.7	-1.8	11.8	-6.2	47.8

[a] - Anova & Dunnett: * = $p \leq 0.05$

FDA-CBER-2021-5683-0767032

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a1]
Group 1: Control	Mean	0.0323	3.3446	2.112	1.357	0.0389
	SD	0.0027	0.5299	0.176	0.356	0.0189
	N	5	5	5	5	5
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0328	3.3192	2.346	1.273	0.0356
	SD	0.0086	0.6362	0.163	0.385	0.0086
	N	5	5	5	5	5
	%Diff	1.3	-0.8	11.1	-6.2	-8.7
Group 3: 10 µg/ animal BNT162a1	Mean	0.0328	2.8093	2.322	1.148	0.0395
	SD	0.0034	0.6543	0.273	0.192	0.0225
	N	5	5	5	5	5
	%Diff	1.4	-16.0	10.0	-15.4	1.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0339	3.2267	2.191	1.203	0.0377
	SD	0.0048	1.1184	0.132	0.131	0.0154
	N	5	5	5	5	5
	%Diff	4.9	-3.5	3.7	-11.3	-3.0

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0767033

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Relative Organ Weights				
		Pituitary (g/kg b.w.) [a]	Prostate Gland (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0373	3.3528	2.324	1.156	0.0388
100 µg/	SD	0.0025	0.5910	0.177	0.319	0.0078
animal	N	5	5	5	5	5
BNT162b1	%Diff	15.3	0.2	10.0	-14.8	-0.2
Group 7:	Mean	0.0334	2.8265	2.288	1.236	0.0314
100 µg/	SD	0.0032	0.7708	0.339	0.191	0.0021
animal	N	5	5	5	5	5
BNT162b2	%Diff	3.4	-15.5	8.3	-8.9	-19.4

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.2274	0.2123	9.151	0.2262	0.2375	4.003
	SD	0.0316	0.0259	0.564	0.0640	0.0591	0.303
	N	10	10	10	10	10	10
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767035

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	4.552	4.757	41.60	7.450	0.0725	0.1139
	SD	0.335	0.446	3.73	0.591	0.0257	0.0464
	N	10	10	10	10	10	10
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767036

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0590	3.913	1.821	0.0480
	SD	0.0088	0.627	0.416	0.0101
	N	10	10	10	10
		-	-	-	-

FDA-CBER-2021-5683-0767037

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a1]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a1]	Heart (g/kg b.w.) [a]
Group 1: Control	Mean	0.2049	0.1977	8.438	0.2449	0.2649	4.156
	SD	0.0375	0.0321	0.235	0.0729	0.0490	0.312
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.2231	0.2225	8.840	0.2666	0.2589	4.144
	SD	0.0359	0.0242	0.638	0.0627	0.0906	0.292
	N	10	10	10	10	10	10
	%Diff	8.9	12.5	4.8	8.8	-2.3	-0.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.2093	0.2102	8.551	0.2683	0.2796	3.963
	SD	0.0329	0.0269	0.662	0.0585	0.0438	0.212
	N	10	10	10	10	10	10
	%Diff	2.1	6.3	1.3	9.5	5.5	-4.6
Group 4: 30 µg/ animal BNT162b1	Mean	0.1981	0.1976	8.146	0.2429	0.2321	4.117
	SD	0.0299	0.0274	0.537	0.0314	0.0252	0.295
	N	10	10	10	10	10	10
	%Diff	-3.3	-0.1	-3.5	-0.9	-12.4	-0.9

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a]	Heart (g/kg b.w.) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	0.2241	0.2189	8.128	0.2372	0.2579	3.824
	SD	0.0255	0.0248	0.768	0.0367	0.0613	0.389
	N	10	10	10	10	10	10
	%Diff	9.4	10.7	-3.7	-3.2	-2.7	-8.0
Group 7: 100 µg/ animal BNT162b2	Mean	0.2280	0.2251	8.598	0.2286	0.2606	3.974
	SD	0.0409	0.0326	0.719	0.0593	0.0643	0.260
	N	10	10	10	10	10	10
	%Diff	11.3	13.9	1.9	-6.7	-1.6	-4.4

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767039

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a1]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a2]
Group 1: Control	Mean	4.255	4.485	37.87	6.054	0.0734	0.1545
	SD	0.293	0.264	2.18	0.486	0.0275	0.0786
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.760**	4.893**	43.81**	7.142**	0.0874	0.1333
	SD	0.279	0.205	2.28	0.782	0.0294	0.0572
	N	10	10	10	10	10	10
	%Diff	11.9	9.1	15.7	18.0	19.2	-13.8
Group 3: 10 µg/ animal BNT162a1	Mean	4.533	4.556	40.61	6.889*	0.0882	0.1801
	SD	0.285	0.207	2.50	0.479	0.0242	0.0424
	N	10	10	10	10	10	10
	%Diff	6.5	1.6	7.2	13.8	20.2	16.5
Group 4: 30 µg/ animal BNT162b1	Mean	4.321	4.448	41.78*	6.777	0.0777	0.1443
	SD	0.207	0.219	3.65	0.599	0.0160	0.1054
	N	10	10	10	10	10	10
	%Diff	1.6	-0.8	10.3	11.9	5.9	-6.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a2] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767040

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	4.529	4.680	43.65**	6.495	0.0757	0.1840
100 µg/	SD	0.369	0.319	4.48	0.915	0.0254	0.0661
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	6.5	4.3	15.3	7.3	3.2	19.1
Group 7:	Mean	4.635*	4.844**	45.66**	6.972*	0.0785	0.1683
100 µg/	SD	0.389	0.254	2.87	0.473	0.0385	0.1062
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	8.9	8.0	20.6	15.2	6.9	8.9

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0767041

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a1]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a2]
Group 1: Control	Mean	0.0679	2.701	2.079	0.0587
	SD	0.0086	0.626	0.472	0.0140
	N	10	10	10	10
	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0620	4.523**	2.089	0.0579
	SD	0.0124	0.737	0.480	0.0182
	N	10	10	10	10
	%Diff	-8.8	67.4	0.5	-1.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.0687	3.395	2.243	0.0526
	SD	0.0079	0.251	0.446	0.0143
	N	10	10	10	10
	%Diff	1.1	25.7	7.9	-10.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0606	3.345	1.955	0.0408*
	SD	0.0122	0.385	0.471	0.0054
	N	10	10	10	10
	%Diff	-10.9	23.8	-5.9	-30.5

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a2] - Anova & Dunnett(Log): * = p ≤ 0.05

FDA-CBER-2021-5683-0767042

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0624	4.035**	1.678	0.0412*
100 µg/	SD	0.0116	0.677	0.327	0.0170
animal	N	10	9	10	10
BNT162b1	%Diff	-8.1	49.4	-19.3	-29.9
Group 7:	Mean	0.0661	4.383**	1.795	0.0507
100 µg/	SD	0.0139	0.496	0.525	0.0190
animal	N	10	10	10	10
BNT162b2	%Diff	-2.7	62.3	-13.6	-13.6

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$

FDA-CBER-2021-5683-0767043

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.1981	0.1926	7.752	0.2609	0.2623	3.760
	SD	0.0302	0.0175	0.664	0.0508	0.0470	0.187
	N	5	5	5	5	5	5
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767044

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	4.163	4.273	35.52	5.596	0.0601	0.1696
	SD	0.178	0.176	1.38	0.336	0.0218	0.0477
	N	5	5	5	5	5	5
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767045

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0644	2.349	1.792	0.0437
	SD	0.0163	0.258	0.283	0.0069
	N	5	5	5	5
		-	-	-	-

FDA-CBER-2021-5683-0767046

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a]	Heart (g/kg b.w.) [a1]
Group 1: Control	Mean	0.2252	0.2232	7.326	0.2286	0.2651	3.804
	SD	0.0279	0.0281	0.511	0.0372	0.0589	0.302
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.1865	0.1744*	7.351	0.2228	0.2578	3.707
	SD	0.0177	0.0356	0.312	0.0542	0.0836	0.225
	N	5	5	5	5	5	5
	%Diff	-17.2	-21.8	0.4	-2.5	-2.7	-2.5
Group 3: 10 µg/ animal BNT162a1	Mean	0.1739	0.1699*	7.465	0.2307	0.2421	3.758
	SD	0.0236	0.0180	0.470	0.0651	0.0534	0.249
	N	5	5	5	5	5	5
	%Diff	-22.8	-23.9	1.9	0.9	-8.7	-1.2
Group 4: 30 µg/ animal BNT162b1	Mean	0.1844	0.1689*	7.309	0.2429	0.2413	3.743
	SD	0.0212	0.0196	0.148	0.0654	0.0552	0.264
	N	5	5	5	5	5	5
	%Diff	-18.1	-24.3	-0.2	6.2	-9.0	-1.6

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0767047

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Adren. Gland (left) (g/kg b.w.) [a]	Adren. Gland (right) (g/kg b.w.) [a]	Brain (g/kg b.w.) [a]	Ovary (left) (g/kg b.w.) [a]	Ovary (right) (g/kg b.w.) [a]	Heart (g/kg b.w.) [a]
Group 5:	Mean	0.2004	0.1979	7.825	0.2633	0.2790	4.287
100 µg/	SD	0.0162	0.0121	0.453	0.0290	0.0270	0.751
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-11.0	-11.3	6.8	15.2	5.2	12.7
Group 7:	Mean	0.2022	0.2081	7.633	0.2086	0.2195	3.956
100 µg/	SD	0.0400	0.0340	0.315	0.0264	0.0298	0.222
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-10.2	-6.7	4.2	-8.8	-17.2	4.0

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767048

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a1]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 1: Control	Mean	4.047	4.280	38.19	5.980	0.0722	0.1331
	SD	0.235	0.363	2.39	0.249	0.0178	0.0632
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	4.060	4.164	38.07	6.155	0.0706	0.1474
	SD	0.282	0.342	2.48	0.719	0.0269	0.0367
	N	5	5	5	5	5	5
	%Diff	0.3	-2.7	-0.3	2.9	-2.2	10.8
Group 3: 10 µg/ animal BNT162a1	Mean	3.985	4.190	34.02*	5.541	0.0674	0.1313
	SD	0.339	0.415	1.34	0.528	0.0174	0.0519
	N	5	5	5	5	5	5
	%Diff	-1.5	-2.1	-10.9	-7.3	-6.6	-1.3
Group 4: 30 µg/ animal BNT162b1	Mean	4.067	4.204	35.36	5.178	0.0717	0.1804
	SD	0.240	0.147	1.62	0.637	0.0224	0.0488
	N	5	5	5	5	5	5
	%Diff	0.5	-1.8	-7.4	-13.4	-0.8	35.5

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767049

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights					
		Kidney (left) (g/kg b.w.) [a]	Kidney (right) (g/kg b.w.) [a]	Liver (g/kg b.w.) [a]	Lungs (g/kg b.w.) [a]	Lymph node (cerv.) (g/kg b.w.) [a]	Lymph node (mesent.) (g/kg b.w.) [a]
Group 5:	Mean	4.289	4.550	39.31	6.208	0.1057	0.1486
100 µg/	SD	0.536	0.568	2.31	0.451	0.0721	0.0295
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	6.0	6.3	2.9	3.8	46.4	11.6
Group 7:	Mean	4.259	4.525	37.99	5.727	0.0617	0.1383
100 µg/	SD	0.554	0.399	2.52	0.132	0.0262	0.0706
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	5.2	5.7	-0.5	-4.2	-14.6	3.9

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 1: Control	Mean	0.0662	2.706	1.943	0.0598
	SD	0.0078	0.367	0.411	0.0118
	N	5	5	5	5
	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0657	2.507	1.638	0.0577
	SD	0.0065	0.305	0.229	0.0159
	N	5	5	5	5
	%Diff	-0.8	-7.4	-15.7	-3.5
Group 3: 10 µg/ animal BNT162a1	Mean	0.0559	2.403	1.778	0.0471
	SD	0.0071	0.158	0.436	0.0136
	N	5	5	5	5
	%Diff	-15.5	-11.2	-8.5	-21.2
Group 4: 30 µg/ animal BNT162b1	Mean	0.0572	2.280	1.550	0.0495
	SD	0.0110	0.171	0.226	0.0086
	N	5	5	5	5
	%Diff	-13.5	-15.8	-20.2	-17.3

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Relative Organ Weights			
		Pituitary (g/kg b.w.) [a]	Spleen (g/kg b.w.) [a]	Thymus (g/kg b.w.) [a]	Thyroid/Par. (left) (g/kg b.w.) [a]
Group 5:	Mean	0.0616	2.885	1.903	0.0442
100 µg/	SD	0.0113	0.235	0.248	0.0071
animal	N	5	5	5	5
BNT162b1	%Diff	-6.8	6.6	-2.0	-26.1
Group 7:	Mean	0.0661	2.749	1.639	0.0433
100 µg/	SD	0.0101	0.249	0.339	0.0120
animal	N	5	5	5	5
BNT162b2	%Diff	-0.1	1.6	-15.6	-27.6

[a] - Anova & Dunnett

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Adren. Gland (left)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Adren. Gland (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Brain	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Epididymis (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Testis (left)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Testis (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Male	Epididymis (left)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	3	Male	Epididymis (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Epididymis (right)	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	17	5	Male	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Male	Epididymis (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Male	Epididymis (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Adren. Gland (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Epididymis (left)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Epididymis (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Testis (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Testis (right)	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Heart	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Male	Kidney (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	2	Male	Lungs	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Male	Kidney (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Heart	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Male	Thyroid/Par. (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	3	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Thymus	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Male	Adren. Gland (left)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	5	Male	Lymph node (mesent.)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Kidney (left)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Kidney (right)	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	2	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	2	Female	Lungs	**	Anova & Dunnett: ** = p ≤ 0.01
	17	3	Female	Lungs	*	Anova & Dunnett: * = p ≤ 0.05
	17	4	Female	Liver	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Kidney (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Kidney (right)	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Lungs	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Spleen	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Female	Thyroid/Par. (left)	*	Anova & Dunnett(Log): * = p ≤ 0.05
	17	5	Female	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Female	Thyroid/Par. (left)	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Female	Spleen	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Female	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05
	38	3	Female	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05
	38	4	Female	Adren. Gland (right)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-1 Relative Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	3	Female	Liver	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
151	0.161	0.146	7.32	1.95	2.07	7.05	8.16
152	0.132	0.142	6.40	1.85	1.68	6.10	5.90
153	0.159	0.167	7.49	1.95	2.27	6.90	7.01
154	0.145	0.137	7.44	1.70	1.63	7.08	7.12
155	0.138	0.156	7.27	1.49	1.42	6.21	6.17
156	0.166	0.154	7.54	2.00	1.96	6.48	6.07
157	0.152	0.148	6.88	1.45	1.62	5.94	6.14
158	0.171	0.146	7.69	1.38	1.42	6.22	6.55
159	0.136	0.114	7.22	1.71	1.57	6.11	6.07
160	0.114	0.122	7.21	1.42	1.65	6.50	6.46
Mean	0.1473	0.1434	7.245	1.690	1.730	6.458	6.565
SD	0.0176	0.0158	0.371	0.241	0.280	0.417	0.693
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
151	4.17	4.79	4.67	42.1	6.36	0.046	0.138
152	3.79	5.21	5.14	37.9	6.13	0.053	0.086
153	3.83	5.50	5.58	39.5	6.46	0.080	0.171
154	3.94	5.13	4.88	40.5	6.86	0.072	0.112
155	3.72	4.82	5.04	41.5	6.99	0.074	0.092
156	4.18	5.09	4.75	41.8	6.03	0.049	0.102
157	3.61	4.62	4.83	41.5	5.30	0.054	0.101
158	5.61	5.41	5.21	42.7	6.96	0.073	0.049
159	3.61	4.50	4.79	40.4	5.43	0.068	0.182
160	3.90	4.77	4.61	38.6	6.34	0.071	0.185
Mean	4.037	4.984	4.949	40.65	6.285	0.0640	0.1218
SD	0.589	0.334	0.296	1.58	0.588	0.0122	0.0457
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
151	0.042	2.842	3.52	2.45	0.061
152	0.040	3.587	3.59	1.78	0.049
153	0.036	3.153	3.55	1.63	0.024
154	0.040	3.873	4.70	1.59	0.033
155	0.039	2.961	4.40	2.34	0.046
156	0.034	2.649	3.32	1.58	0.045
157	0.034	2.214	3.17	1.25	0.027
158	0.033	2.762	3.74	1.63	0.045
159	0.039	2.333	3.47	1.50	0.043
160	0.035	2.233	4.29	1.38	0.032
Mean	0.0371	2.8607	3.775	1.713	0.0405
SD	0.0032	0.5571	0.508	0.389	0.0115
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
166	0.224	0.234	9.06	0.203	0.219	4.58
167	0.203	0.198	9.27	0.198	0.213	3.97
168	0.240	0.223	10.12	0.280	0.354	3.95
169	0.244	0.229	9.32	0.331	0.311	3.82
170	0.156	0.156	8.13	0.196	0.191	4.44
171	0.234	0.202	9.50	0.104	0.145	3.74
172	0.210	0.216	8.83	0.242	0.242	4.10
173	0.267	0.251	8.95	0.295	0.251	3.98
174	0.245	0.213	9.70	0.208	0.213	3.62
175	0.250	0.201	8.63	0.206	0.235	3.82
Mean	0.2274	0.2123	9.151	0.2262	0.2375	4.003
SD	0.0316	0.0259	0.564	0.0640	0.0591	0.303
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
166	4.42	5.00	45.8	7.65	0.026	0.078
167	4.61	4.91	40.7	7.68	0.059	0.099
168	5.03	5.37	41.2	6.29	0.069	0.137
169	4.94	5.09	43.3	7.43	0.122	0.183
170	4.09	4.00	36.9	6.80	0.089	0.173
171	4.26	4.67	37.4	7.68	0.093	0.088
172	4.42	4.21	43.6	8.15	0.058	0.074
173	5.02	5.24	48.6	7.59	0.076	0.082
174	4.37	4.48	38.9	7.04	0.059	0.165
175	4.36	4.61	39.7	8.19	0.074	0.059
Mean	4.552	4.757	41.60	7.450	0.0725	0.1139
SD	0.335	0.446	3.73	0.591	0.0257	0.0464
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
166	0.062	4.06	2.45	0.031
167	0.055	3.27	1.74	0.040
168	0.051	3.49	1.83	0.051
169	0.076	3.36	1.99	0.061
170	0.058	3.96	1.91	0.040
171	0.062	4.00	0.93	0.057
172	0.047	4.36	1.37	0.053
173	0.055	5.13	2.13	0.060
174	0.069	3.09	1.87	0.048
175	0.054	4.41	2.01	0.039
Mean	0.0590	3.913	1.821	0.0480
SD	0.0088	0.627	0.416	0.0101
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
1	0.108	0.096	6.28	1.85	1.34	5.86	5.90
2	0.130	0.114	6.35	1.46	1.27	6.54	6.25
3	0.131	0.116	6.31	1.64	1.34	5.21	5.15
4	0.105	0.108	5.85	1.20	1.23	5.19	4.80
5	0.110	0.122	6.15	1.16	1.26	5.35	5.41
6	0.111	0.087	6.10	1.17	1.23	5.32	5.44
7	0.110	0.094	6.45	1.42	1.48	5.13	5.19
8	0.146	0.137	5.97	1.58	1.43	5.88	5.76
9	0.115	0.103	6.11	1.20	1.12	5.32	5.41
10	0.100	0.103	5.85	1.33	1.15	5.32	5.17
Mean	0.1167	0.1081	6.141	1.401	1.284	5.511	5.447
SD	0.0144	0.0149	0.207	0.233	0.114	0.448	0.421
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
31	0.148	0.137	7.17	1.63	1.48	6.76	6.54
32	0.178	0.155	7.41	1.78	1.90	6.75	6.71
33	0.183	0.200	6.84	1.63	1.43	6.10	6.24
34	0.160	0.153	6.50	1.70	1.56	6.29	6.39
35	0.129	0.143	6.86	1.75	1.57	6.18	6.14
36	0.146	0.116	7.51	1.64	1.42	6.02	5.87
37	0.143	0.128	7.26	1.36	1.50	6.38	6.67
38	0.124	0.149	7.09	1.70	1.74	6.39	6.63
39	0.173	0.173	8.25	1.65	1.86	7.32	7.28
40	0.144	0.144	7.07	1.66	1.74	6.03	6.25
Mean	0.1529	0.1498	7.195	1.652	1.621	6.421	6.472
SD	0.0203	0.0235	0.473	0.116	0.176	0.411	0.388
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
61	0.108	0.120	5.65	1.83	1.71	5.97	6.08
62	0.126	0.139	6.25	1.42	1.39	5.86	5.86
63	0.110	0.113	5.58	2.24	1.98	6.22	6.01
64	0.108	0.121	6.09	1.79	1.82	5.63	5.69
65	0.119	0.107	5.79	1.54	1.40	5.85	5.82
66	0.115	0.100	6.77	1.87	1.75	5.74	5.49
67	0.130	0.127	5.72	1.91	1.77	5.32	5.63
68	0.119	0.133	6.81	1.94	1.51	6.41	6.05
69	0.140	0.147	6.19	1.56	1.40	5.04	5.10
70	0.161	0.155	5.76	1.47	1.21	5.14	5.17
Mean	0.1237	0.1261	6.061	1.759	1.595	5.717	5.690
SD	0.0165	0.0176	0.447	0.256	0.244	0.446	0.348
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
91	0.111	0.091	6.25	1.53	1.33	5.99	5.82
92	0.134	0.121	7.00	1.62	1.55	5.55	5.62
93	0.127	0.110	6.27	1.67	1.53	6.00	5.74
94	0.142	0.149	6.50	1.31	1.42	5.70	5.63
95	0.159	0.159	6.28	1.69	1.36	6.02	5.98
96	0.142	0.124	6.07	1.63	1.63	5.53	5.44
97	0.139	0.109	6.70	1.62	1.62	5.70	5.50
98	0.167	0.177	6.88	1.84	1.74	6.81	6.95
99	0.122	0.122	6.31	1.78	1.69	5.97	5.90
100	0.141	0.138	6.61	1.48	1.38	5.74	5.81
Mean	0.1383	0.1299	6.487	1.617	1.525	5.901	5.840
SD	0.0165	0.0258	0.304	0.151	0.146	0.369	0.426
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
121	0.090	0.111	6.36	2.14	1.84	6.45	6.30
122	0.121	0.125	6.98	1.76	1.69	6.03	6.28
123	0.166	0.186	6.45	1.56	1.69	6.91	6.06
124	0.091	0.110	5.99	1.40	1.51	5.00	5.06
125	0.183	0.148	7.01	1.80	2.45	5.84	5.97
126	0.135	0.123	5.63	1.58	1.50	5.13	4.96
127	0.171	0.181	6.19	1.78	1.55	5.63	5.66
128	0.151	0.126	6.92	1.77	1.62	7.28	6.88
129	0.136	0.130	6.45	1.73	1.73	6.01	5.98
130	0.153	0.143	6.34	1.79	1.96	5.65	5.51
Mean	0.1398	0.1383	6.432	1.731	1.754	5.992	5.867
SD	0.0318	0.0266	0.445	0.193	0.285	0.722	0.587
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
181	0.118	0.112	5.92	1.61	1.70	5.98	6.07
182	0.118	0.114	7.03	1.62	1.62	5.86	6.04
183	0.136	0.115	6.61	1.80	1.49	5.94	5.94
184	0.171	0.174	6.66	1.50	1.37	5.88	5.74
185	0.145	0.133	5.66	1.57	1.66	5.89	5.92
186	0.152	0.129	7.41	1.94	1.90	7.26	6.72
187	0.150	0.047	6.55	1.70	1.50	5.92	5.72
188	0.141	0.121	6.18	1.99	1.73	6.41	6.57
189	0.123	0.119	6.86	2.15	1.77	6.72	6.45
190	0.186	0.183	6.48	2.69	2.46	5.95	5.72
Mean	0.1439	0.1248	6.537	1.857	1.720	6.180	6.090
SD	0.0223	0.0372	0.518	0.359	0.302	0.471	0.367
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
1	3.66	4.75	4.97	39.8	5.26	0.064	0.105
2	3.48	4.59	4.88	41.7	6.41	0.059	0.137
3	3.57	4.29	4.35	42.3	5.54	0.068	0.191
4	3.27	4.53	4.89	37.5	4.98	0.039	0.063
5	3.48	4.25	4.38	40.3	5.19	0.145	0.064
6	3.54	4.14	4.23	40.5	5.05	0.027	0.033
7	3.62	4.25	4.12	41.2	10.41	0.044	0.097
8	3.61	4.03	4.15	38.2	5.58	0.084	0.101
9	3.26	4.70	4.73	39.1	5.96	0.050	0.062
10	3.43	4.17	4.61	38.4	5.08	0.065	0.157
Mean	3.493	4.369	4.531	39.90	5.945	0.0644	0.1010
SD	0.140	0.252	0.325	1.59	1.632	0.0326	0.0487
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
31	3.95	4.92	4.88	38.1	6.76	0.085	0.248
32	3.64	5.82	5.89	42.3	7.44	0.074	0.225
33	4.03	5.04	5.20	41.7	7.00	0.073	0.120
34	3.48	4.69	4.65	39.8	6.57	0.060	0.078
35	4.54	4.79	4.54	41.4	6.00	0.061	0.164
36	3.81	4.49	4.60	41.5	6.28	0.064	0.112
37	3.67	4.44	4.58	37.0	7.00	0.066	0.062
38	5.36	5.00	5.11	31.6	8.66	0.074	0.188
39	4.02	5.03	5.67	39.8	6.30	0.080	0.131
40	3.74	4.00	4.07	36.3	6.03	0.092	0.100
Mean	4.024	4.819	4.919	38.93	6.805	0.0730	0.1428
SD	0.551	0.481	0.556	3.31	0.799	0.0107	0.0618
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
61	3.31	4.03	4.25	37.4	5.51	0.054	0.100
62	3.18	4.57	4.70	41.7	6.15	0.053	0.175
63	3.37	4.12	4.44	35.7	5.93	0.038	0.073
64	3.50	4.55	4.67	35.6	5.51	0.062	0.139
65	3.53	4.72	4.45	43.3	5.49	0.059	0.157
66	4.03	4.68	4.59	40.9	6.34	0.078	0.091
67	3.27	4.25	4.65	36.9	6.53	0.059	0.107
68	3.75	4.61	4.25	39.6	6.34	0.076	0.061
69	4.21	4.47	4.50	40.2	6.92	0.061	0.064
70	3.47	3.78	4.09	39.2	6.92	0.040	0.237
Mean	3.561	4.377	4.459	39.05	6.163	0.0579	0.1204
SD	0.336	0.315	0.205	2.60	0.548	0.0130	0.0566
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
91	4.07	4.49	4.56	37.7	6.64	0.075	0.159
92	3.41	4.69	4.86	34.5	5.14	0.045	0.231
93	3.63	4.73	4.23	38.7	6.17	0.053	0.120
94	4.11	4.91	5.22	43.9	6.71	0.031	0.038
95	3.87	4.86	4.79	39.7	5.75	0.040	0.066
96	3.32	4.41	4.50	39.0	5.92	0.248	0.151
97	3.32	4.14	4.81	37.1	5.37	0.060	0.073
98	3.65	5.18	4.83	41.0	5.73	0.059	0.094
99	3.12	4.59	4.43	38.1	5.53	0.059	0.134
100	3.73	4.43	4.67	37.6	6.08	0.070	0.030
Mean	3.623	4.644	4.690	38.73	5.903	0.0740	0.1097
SD	0.331	0.296	0.275	2.50	0.511	0.0625	0.0620
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
121	4.64	4.40	4.46	39.8	5.88	0.057	0.063
122	3.71	5.18	4.81	41.2	7.57	0.029	0.301
123	3.71	4.76	4.69	42.0	6.19	0.033	0.088
124	3.66	4.59	4.81	41.8	6.52	0.052	0.074
125	3.59	4.73	4.66	41.4	5.80	0.076	0.173
126	3.73	4.78	4.78	47.5	6.34	0.100	0.205
127	3.62	5.17	4.64	39.5	5.79	0.086	0.128
128	3.64	4.18	4.29	43.6	6.38	0.072	0.231
129	3.79	4.95	4.88	37.5	5.42	0.050	0.113
130	3.62	5.35	5.41	52.1	6.11	0.046	0.086
Mean	3.771	4.809	4.745	42.65	6.199	0.0601	0.1463
SD	0.311	0.365	0.296	4.27	0.585	0.0228	0.0788
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
181	3.92	4.28	4.46	39.2	5.62	0.043	0.052
182	3.57	4.83	5.12	38.3	6.37	0.063	0.169
183	3.39	4.55	4.82	42.1	6.24	0.041	0.319
184	4.58	4.61	4.68	40.3	5.60	0.061	0.085
185	3.47	4.35	4.21	42.7	6.31	0.068	0.157
186	3.88	5.28	5.43	43.7	6.50	0.084	0.327
187	3.66	4.06	4.22	38.6	7.12	0.050	0.213
188	3.96	4.51	4.71	40.5	5.69	0.029	0.078
189	3.89	5.22	5.42	38.9	5.73	0.051	0.167
190	3.69	4.99	5.02	42.6	7.68	0.040	0.120
Mean	3.799	4.667	4.810	40.68	6.286	0.0529	0.1687
SD	0.336	0.404	0.442	1.95	0.689	0.0161	0.0948
N	10	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
1	0.045	2.001	2.20	1.43	0.041
2	0.039	3.359	2.86	1.89	0.059
3	0.045	2.764	2.44	1.94	0.036
4	0.039	3.360	1.89	1.23	0.039
5	0.032	3.067	2.48	1.55	0.048
6	0.036	2.186	2.88	1.71	0.033
7	0.035	2.852	2.96	1.73	0.025
8	0.039	3.604	3.10	1.58	0.033
9	0.038	2.644	2.47	2.14	0.047
10	0.044	2.573	2.39	1.27	0.041
Mean	0.0391	2.8411	2.568	1.647	0.0402
SD	0.0043	0.5188	0.378	0.294	0.0095
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
31	0.041	3.149	4.18	1.59	0.055
32	0.047	2.485	2.87	1.86	0.054
33	0.040	2.447	3.80	2.13	0.047
34	0.043	2.887	3.87	1.56	0.050
35	0.046	4.789	3.75	2.07	0.039
36	0.064	2.621	3.70	1.79	0.045
37	0.055	2.285	3.34	1.17	0.066
38	0.032	2.153	3.16	1.67	0.050
39	0.047	2.919	3.55	1.35	0.055
40	0.041	3.270	3.63	1.74	0.048
Mean	0.0454	2.9005	3.584	1.695	0.0509
SD	0.0087	0.7572	0.377	0.297	0.0073
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
61	0.040	2.172	3.05	1.17	0.031
62	0.030	2.210	2.98	1.85	0.043
63	0.041	3.151	3.43	1.19	0.038
64	0.037	2.465	3.19	1.33	0.037
65	0.033	2.132	2.97	1.87	0.024
66	0.044	3.374	3.34	1.31	0.034
67	0.045	3.109	3.58	1.63	0.059
68	0.050	3.576	2.99	1.80	0.040
69	0.045	3.037	3.67	2.33	0.041
70	0.034	1.741	3.64	1.69	0.031
Mean	0.0398	2.6968	3.283	1.618	0.0379
SD	0.0064	0.6254	0.284	0.369	0.0094
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
91	0.039	2.545	3.29	1.53	0.049
92	0.048	2.359	2.52	1.38	0.048
93	0.033	3.338	3.10	1.77	0.053
94	0.035	2.872	3.35	1.76	0.038
95	0.053	3.038	2.94	2.05	0.033
96	0.048	2.579	3.38	1.66	0.042
97	0.036	2.735	3.15	1.23	0.036
98	0.042	2.599	3.75	1.91	0.042
99	0.044	3.788	2.97	1.25	0.047
100	0.037	2.041	2.95	0.94	0.054
Mean	0.0415	2.7895	3.141	1.548	0.0443
SD	0.0066	0.5007	0.332	0.347	0.0071
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
121	0.048	2.118	3.68	1.54	0.042
122	0.026	1.988	3.34	1.43	0.033
123	0.036	2.978	3.75	1.56	0.033
124	0.033	2.785	2.80	1.54	0.036
125	0.048	2.445	3.35	1.24	0.041
126	0.041	2.473	3.75	1.17	0.038
127	0.046	3.291	2.73	1.22	0.033
128	0.032	1.290	3.64	1.15	0.025
129	0.037	-	2.99	1.20	0.033
130	0.037	3.411	3.35	1.99	0.023
Mean	0.0384	2.5310	3.339	1.405	0.0338
SD	0.0075	0.6737	0.383	0.264	0.0061
N	10	9	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
181	0.039	2.909	3.49	0.82	0.021
182	0.041	2.446	3.17	1.25	0.048
183	0.044	3.311	3.36	1.02	0.024
184	0.041	2.040	3.59	1.33	0.048
185	0.033	3.525	3.61	1.01	0.030
186	0.038	2.967	3.65	0.87	0.049
187	0.037	2.269	3.19	0.86	0.033
188	0.029	2.468	3.24	3.04	0.026
189	0.041	3.336	3.96	1.33	0.048
190	0.037	1.825	3.82	1.43	0.043
Mean	0.0379	2.7095	3.508	1.297	0.0370
SD	0.0043	0.5848	0.268	0.651	0.0113
N	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
16	0.253	0.240	8.36	0.232	0.257	3.90
17	0.215	0.220	8.33	0.394	0.330	4.16
18	0.137	0.152	8.54	0.324	0.334	4.42
19	0.166	0.157	8.67	0.125	0.277	4.61
20	0.186	0.217	8.43	0.231	0.262	3.81
21	0.190	0.171	8.61	0.264	0.204	4.26
22	0.256	0.241	8.83	0.198	0.290	4.58
23	0.225	0.188	8.41	0.234	0.285	4.14
24	0.194	0.186	8.10	0.249	0.186	3.92
25	0.226	0.205	8.10	0.200	0.226	3.75
Mean	0.2049	0.1977	8.438	0.2449	0.2649	4.156
SD	0.0375	0.0321	0.235	0.0729	0.0490	0.312
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
46	0.254	0.240	8.31	0.301	0.423	4.04
47	0.176	0.185	8.66	0.213	0.157	4.17
48	0.232	0.204	8.04	0.282	0.132	4.31
49	0.160	0.243	9.61	0.180	0.194	3.78
50	0.267	0.234	8.58	0.239	0.220	3.84
51	0.259	0.243	9.67	0.207	0.228	4.40
52	0.208	0.179	9.13	0.232	0.256	4.54
53	0.201	0.237	9.32	0.322	0.322	4.48
54	0.231	0.236	9.20	0.381	0.318	4.14
55	0.244	0.224	7.88	0.310	0.339	3.72
Mean	0.2231	0.2225	8.840	0.2666	0.2589	4.144
SD	0.0359	0.0242	0.638	0.0627	0.0906	0.292
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
76	0.182	0.182	8.07	0.326	0.271	4.24
77	0.219	0.219	9.04	0.205	0.214	3.73
78	0.191	0.200	8.46	0.235	0.289	3.77
79	0.259	0.251	7.61	0.223	0.211	4.01
80	0.258	0.205	9.53	0.395	0.305	3.89
81	0.244	0.216	8.90	0.295	0.333	4.08
82	0.186	0.170	7.54	0.268	0.340	4.26
83	0.193	0.198	8.97	0.265	0.289	3.66
84	0.187	0.206	8.32	0.210	0.252	4.11
85	0.175	0.255	9.07	0.260	0.293	3.88
Mean	0.2093	0.2102	8.551	0.2683	0.2796	3.963
SD	0.0329	0.0269	0.662	0.0585	0.0438	0.212
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
106	0.180	0.189	7.76	0.210	0.206	4.03
107	0.216	0.216	8.47	0.264	0.207	3.93
108	0.194	0.185	8.36	0.236	0.259	3.79
109	0.168	0.157	7.61	0.180	0.203	4.55
110	0.211	0.241	7.71	0.220	0.220	3.96
111	0.169	0.173	7.37	0.258	0.238	4.15
112	0.270	0.237	8.72	0.280	0.228	4.55
113	0.184	0.179	7.91	0.273	0.228	4.00
114	0.198	0.207	8.62	0.250	0.278	4.43
115	0.191	0.191	8.92	0.259	0.255	3.78
Mean	0.1981	0.1976	8.146	0.2429	0.2321	4.117
SD	0.0299	0.0274	0.537	0.0314	0.0252	0.295
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
136	0.240	0.220	8.31	0.183	0.183	4.24
137	0.250	0.226	8.57	0.301	0.344	3.63
138	0.196	0.212	6.83	0.220	0.200	3.18
139	0.198	0.181	8.20	0.247	0.243	3.79
140	0.229	0.224	8.77	0.238	0.295	4.34
141	0.208	0.224	7.81	0.220	0.204	3.82
142	0.248	0.219	9.62	0.262	0.335	4.37
143	0.197	0.184	7.99	0.184	0.202	3.77
144	0.209	0.230	7.42	0.267	0.320	3.45
145	0.266	0.270	7.76	0.249	0.253	3.65
Mean	0.2241	0.2189	8.128	0.2372	0.2579	3.824
SD	0.0255	0.0248	0.768	0.0367	0.0613	0.389
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
196	0.161	0.201	7.69	0.177	0.233	3.86
197	0.243	0.228	8.94	0.248	0.214	4.27
198	0.199	0.179	8.72	0.314	0.334	4.19
199	0.308	0.282	9.23	0.246	0.395	3.95
200	0.241	0.237	7.60	0.121	0.201	3.38
201	0.237	0.227	9.28	0.218	0.222	4.12
202	0.261	0.266	9.31	0.281	0.276	3.89
203	0.213	0.231	8.49	0.293	0.267	3.82
204	0.188	0.183	7.59	0.192	0.277	4.18
205	0.230	0.216	9.15	0.197	0.188	4.08
Mean	0.2280	0.2251	8.598	0.2286	0.2606	3.974
SD	0.0409	0.0326	0.719	0.0593	0.0643	0.260
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
16	4.80	4.59	41.2	5.92	0.051	0.090
17	4.12	4.71	36.6	5.72	0.142	0.165
18	4.37	4.56	36.3	6.53	0.069	0.240
19	4.06	3.97	41.1	7.10	0.078	0.083
20	3.81	4.04	35.0	6.12	0.044	0.067
21	4.17	4.58	37.0	5.46	0.069	0.134
22	4.68	4.54	40.1	6.27	0.087	0.212
23	4.18	4.73	37.7	5.88	0.064	0.193
24	4.18	4.60	35.8	5.57	0.076	0.291
25	4.18	4.53	37.9	5.97	0.052	0.070
Mean	4.255	4.485	37.87	6.054	0.0734	0.1545
SD	0.293	0.264	2.18	0.486	0.0275	0.0786
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
46	5.03	5.17	44.6	6.90	0.113	0.183
47	4.63	4.82	42.6	7.55	0.097	0.083
48	4.31	4.59	43.6	6.13	0.036	0.245
49	5.14	5.05	41.2	7.08	0.078	0.082
50	4.64	4.74	41.3	7.69	0.066	0.113
51	5.07	5.02	48.6	7.19	0.057	0.088
52	4.88	4.83	43.5	8.59	0.082	0.087
53	4.88	5.19	46.3	5.79	0.106	0.101
54	4.53	4.67	43.8	7.27	0.135	0.183
55	4.49	4.87	42.5	7.21	0.105	0.167
Mean	4.760	4.893	43.81	7.142	0.0874	0.1333
SD	0.279	0.205	2.28	0.782	0.0294	0.0572
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
76	4.38	4.62	43.4	7.56	0.107	0.191
77	4.94	4.66	41.9	7.64	0.135	0.256
78	4.50	4.55	39.6	6.21	0.098	0.220
79	4.66	4.62	40.9	6.28	0.085	0.109
80	4.84	4.79	39.5	6.74	0.095	0.158
81	4.78	4.50	43.1	6.98	0.052	0.141
82	4.42	4.42	40.7	6.87	0.059	0.213
83	4.58	4.15	37.1	6.99	0.077	0.174
84	4.16	4.39	43.5	7.11	0.098	0.159
85	4.06	4.87	36.4	6.52	0.076	0.180
Mean	4.533	4.556	40.61	6.889	0.0882	0.1801
SD	0.285	0.207	2.50	0.479	0.0242	0.0424
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
106	4.54	4.71	41.6	6.17	0.090	0.231
107	4.36	4.41	36.7	6.61	0.073	0.056
108	4.53	4.62	41.6	6.61	0.051	0.139
109	4.21	4.36	45.9	7.12	0.088	0.092
110	3.92	4.05	41.3	5.68	0.099	0.082
111	4.43	4.59	39.1	6.93	0.056	0.048
112	4.46	4.69	44.6	7.54	0.081	0.100
113	4.28	4.28	47.3	7.01	0.086	0.077
114	4.43	4.52	43.4	7.63	0.090	0.372
115	4.05	4.23	36.4	6.46	0.064	0.246
Mean	4.321	4.448	41.78	6.777	0.0777	0.1443
SD	0.207	0.219	3.65	0.599	0.0160	0.1054
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
136	5.01	4.60	47.7	6.97	0.106	0.155
137	4.38	4.62	41.9	6.92	0.071	0.151
138	3.65	3.92	34.9	5.53	0.043	0.133
139	4.32	4.50	38.4	6.97	0.062	0.225
140	4.76	4.76	44.8	6.62	0.086	0.071
141	4.74	5.07	44.0	6.90	0.042	0.187
142	4.61	4.76	44.2	7.14	0.112	0.136
143	4.74	4.78	47.4	5.79	0.088	0.241
144	4.55	4.76	50.0	4.55	0.053	0.267
145	4.52	5.02	43.2	7.56	0.095	0.274
Mean	4.529	4.680	43.65	6.495	0.0757	0.1840
SD	0.369	0.319	4.48	0.915	0.0254	0.0661
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
196	4.31	4.39	44.7	7.24	0.020	0.093
197	4.66	4.86	46.6	7.38	0.034	0.058
198	4.38	4.68	49.3	6.33	0.110	0.169
199	4.67	4.97	44.6	6.77	0.118	0.221
200	4.02	4.70	41.0	6.84	0.044	0.225
201	5.30	4.64	49.7	7.15	0.071	0.099
202	5.17	4.92	44.8	6.99	0.108	0.123
203	4.44	5.20	45.3	7.37	0.116	0.422
204	4.56	4.86	42.2	6.10	0.051	0.183
205	4.83	5.21	48.3	7.56	0.113	0.089
Mean	4.635	4.844	45.66	6.972	0.0785	0.1683
SD	0.389	0.254	2.87	0.473	0.0385	0.1062
N	10	10	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
16	0.064	2.10	1.97	0.047
17	0.069	2.65	2.38	0.059
18	0.059	2.26	3.19	0.044
19	0.065	4.38	1.48	0.069
20	0.080	2.57	1.91	0.049
21	0.060	2.45	2.31	0.051
22	0.077	2.56	2.08	0.092
23	0.069	2.85	1.70	0.064
24	0.080	2.57	1.90	0.059
25	0.057	2.61	1.87	0.052
Mean	0.0679	2.701	2.079	0.0587
SD	0.0086	0.626	0.472	0.0140
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
46	0.070	4.32	2.54	0.056
47	0.042	3.52	2.45	0.032
48	0.064	4.13	1.91	0.054
49	0.053	4.85	2.57	0.058
50	0.066	4.83	1.31	0.080
51	0.067	4.29	2.59	0.036
52	0.053	5.94	2.27	0.077
53	0.065	5.04	1.61	0.050
54	0.087	4.82	1.49	0.087
55	0.053	3.49	2.15	0.048
Mean	0.0620	4.523	2.089	0.0579
SD	0.0124	0.737	0.480	0.0182
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
76	0.070	3.50	2.33	0.051
77	0.070	3.21	2.47	0.037
78	0.068	3.37	2.44	0.064
79	0.061	2.88	1.94	0.053
80	0.074	3.58	2.11	0.074
81	0.056	3.28	2.11	0.042
82	0.075	3.32	2.37	0.039
83	0.058	3.81	1.59	0.053
84	0.079	3.55	3.23	0.037
85	0.076	3.45	1.84	0.076
Mean	0.0687	3.395	2.243	0.0526
SD	0.0079	0.251	0.446	0.0143
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
106	0.069	3.30	2.10	0.043
107	0.065	2.90	2.20	0.039
108	0.046	3.47	1.99	0.046
109	0.054	3.71	2.87	0.046
110	0.086	3.32	1.34	0.039
111	0.056	4.03	2.22	0.036
112	0.071	2.80	1.52	0.043
113	0.057	3.59	2.12	0.029
114	0.047	3.39	1.89	0.042
115	0.055	2.96	1.32	0.045
Mean	0.0606	3.345	1.955	0.0408
SD	0.0122	0.385	0.471	0.0054
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
136	0.069	4.77	2.24	0.029
137	0.080	3.91	1.46	0.080
138	0.047	2.43	1.18	0.031
139	0.066	3.92	1.68	0.053
140	0.062	4.72	1.67	0.024
141	0.058	4.20	1.33	0.029
142	0.073	4.18	1.70	0.049
143	0.061	4.17	2.15	0.031
144	0.041	-	1.72	0.037
145	0.066	4.03	1.66	0.050
Mean	0.0624	4.035	1.678	0.0412
SD	0.0116	0.677	0.327	0.0170
N	10	9	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
196	0.056	4.79	1.53	0.044
197	0.068	4.52	1.60	0.039
198	0.060	4.63	1.79	0.045
199	0.087	3.74	1.64	0.082
200	0.056	3.54	1.41	0.032
201	0.052	4.40	3.03	0.085
202	0.094	4.53	2.17	0.059
203	0.067	3.95	1.95	0.031
204	0.055	4.56	1.75	0.043
205	0.066	5.16	1.08	0.047
Mean	0.0661	4.383	1.795	0.0507
SD	0.0139	0.496	0.525	0.0190
N	10	10	10	10

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
161	0.120	0.115	4.99	1.71	1.81	4.70	4.75
162	0.101	0.091	6.43	1.86	1.98	5.67	5.64
163	0.082	0.089	5.28	1.61	1.71	4.95	5.05
164	0.092	0.114	5.60	2.06	2.09	5.40	7.35
165	0.111	0.088	5.41	1.65	1.78	5.13	5.13
Mean	0.1009	0.0995	5.544	1.777	1.874	5.170	5.584
SD	0.0152	0.0138	0.546	0.185	0.156	0.381	1.038
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
161	3.95	4.38	4.78	39.5	6.22	0.043	0.093
162	3.42	4.57	4.57	34.8	4.97	0.037	0.070
163	3.47	3.78	3.55	34.7	6.38	0.066	0.166
164	2.95	4.06	4.29	35.7	5.23	0.037	0.100
165	3.63	4.33	4.64	34.3	7.55	0.062	0.126
Mean	3.483	4.223	4.365	35.79	6.070	0.0489	0.1111
SD	0.365	0.309	0.490	2.13	1.026	0.0141	0.0366
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
161	0.037	3.100	2.27	0.96	0.048
162	0.037	3.303	1.95	0.95	0.034
163	0.041	2.440	2.65	1.20	0.048
164	0.029	2.739	2.14	1.23	0.023
165	0.031	2.331	2.19	1.21	0.046
Mean	0.0349	2.7828	2.242	1.109	0.0399
SD	0.0050	0.4167	0.258	0.143	0.0113
N	5	5	5	5	5

FDA-CBER-2021-5683-0767106

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
176	0.217	0.217	7.73	0.299	0.262	3.66
177	0.233	0.199	8.14	0.242	0.305	3.69
178	0.187	0.169	8.06	0.191	0.191	4.09
179	0.154	0.188	8.22	0.321	0.248	3.68
180	0.199	0.189	6.61	0.252	0.304	3.67
Mean	0.1981	0.1926	7.752	0.2609	0.2623	3.760
SD	0.0302	0.0175	0.664	0.0508	0.0470	0.187
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
176	4.12	4.30	35.3	5.92	0.050	0.154
177	3.90	3.98	34.3	5.04	0.055	0.233
178	4.27	4.36	37.8	5.56	0.098	0.205
179	4.15	4.45	35.5	5.78	0.056	0.120
180	4.37	4.27	34.6	5.67	0.042	0.136
Mean	4.163	4.273	35.52	5.596	0.0601	0.1696
SD	0.178	0.176	1.38	0.336	0.0218	0.0477
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
176	0.081	2.76	2.26	0.041
177	0.064	2.08	1.53	0.042
178	0.080	2.27	1.82	0.053
179	0.051	2.23	1.67	0.047
180	0.045	2.41	1.68	0.035
Mean	0.0644	2.349	1.792	0.0437
SD	0.0163	0.258	0.283	0.0069
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
11	0.092	0.105	5.65	1.70	1.62	5.65	5.70
12	0.111	0.116	5.39	1.86	1.75	5.00	4.85
13	0.108	0.106	4.96	2.06	1.82	4.81	4.84
14	0.078	0.084	5.57	2.04	1.87	5.32	5.48
15	0.101	0.084	5.22	1.58	1.48	6.35	9.03
Mean	0.0979	0.0988	5.356	1.847	1.709	5.426	5.980
SD	0.0132	0.0144	0.278	0.212	0.160	0.607	1.749
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
41	0.132	0.146	5.49	2.03	2.11	5.38	5.55
42	0.124	0.124	5.54	1.66	1.71	5.26	5.42
43	0.108	0.094	4.96	1.46	1.46	4.75	4.80
44	0.130	0.132	5.35	1.72	1.64	4.77	-
45	0.108	0.090	5.21	2.14	1.93	4.97	4.79
Mean	0.1204	0.1172	5.311	1.803	1.772	5.025	5.139
SD	0.0116	0.0247	0.232	0.278	0.253	0.284	0.404
N	5	5	5	5	5	5	4

FDA-CBER-2021-5683-0767111

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
71	0.102	0.100	5.23	2.00	1.97	4.48	4.33
72	0.112	0.090	5.52	2.15	1.96	5.07	5.07
73	0.117	0.125	5.42	1.88	1.96	4.99	5.26
74	0.097	0.092	4.98	1.85	1.90	5.00	4.88
75	0.111	0.117	5.13	2.01	2.19	5.58	5.56
Mean	0.1078	0.1051	5.257	1.977	1.997	5.024	5.021
SD	0.0080	0.0156	0.221	0.120	0.112	0.390	0.457
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
101	0.095	0.095	5.50	1.67	1.61	5.39	5.17
102	0.094	0.072	5.41	1.66	1.71	5.06	5.09
103	0.080	0.069	4.74	1.46	1.22	6.40	8.51
104	0.077	0.096	4.60	1.47	1.37	4.60	4.62
105	0.094	0.106	5.08	2.09	1.82	4.68	4.68
Mean	0.0878	0.0874	5.065	1.671	1.547	5.227	5.614
SD	0.0084	0.0161	0.398	0.256	0.249	0.730	1.635
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767113

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
131	0.090	0.100	5.08	1.88	1.78	4.87	4.75
132	0.099	0.101	5.74	2.11	2.08	5.02	5.07
133	0.108	0.102	5.64	2.29	2.10	4.39	4.48
134	0.094	0.094	5.39	2.31	2.09	5.32	5.32
135	0.120	0.104	5.13	1.86	1.99	5.61	5.77
Mean	0.1022	0.1003	5.396	2.090	2.009	5.042	5.077
SD	0.0117	0.0036	0.293	0.217	0.134	0.460	0.500
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767114

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Epididymis (left) (g/kg b.w.)	Epididymis (right) (g/kg b.w.)	Testis (left) (g/kg b.w.)	Testis (right) (g/kg b.w.)
191	0.109	0.115	5.63	1.68	1.74	5.24	5.63
192	0.087	0.100	4.81	1.98	2.00	5.37	4.88
193	0.073	0.075	4.75	1.68	1.56	4.75	4.77
194	0.095	0.083	6.21	1.87	1.90	5.52	5.70
195	0.100	0.112	5.29	2.20	2.15	5.26	5.19
Mean	0.0929	0.0972	5.337	1.882	1.869	5.229	5.235
SD	0.0136	0.0175	0.607	0.218	0.229	0.291	0.423
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767115

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
11	3.30	4.45	4.84	31.4	5.96	0.058	0.058
12	3.32	4.28	4.46	37.6	4.61	0.067	0.057
13	3.39	4.25	4.49	38.3	4.91	0.054	0.052
14	3.39	4.36	4.95	35.0	5.65	0.042	0.090
15	3.05	4.55	4.50	33.2	5.27	0.030	0.071
Mean	3.289	4.378	4.649	35.10	5.281	0.0500	0.0653
SD	0.138	0.125	0.229	2.91	0.545	0.0145	0.0154
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767116

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
41	3.58	4.22	4.51	34.4	6.14	0.051	0.096
42	3.46	4.69	4.89	38.2	5.82	0.121	0.098
43	3.14	3.76	3.88	35.5	5.76	0.026	0.046
44	3.47	4.11	3.87	37.6	5.64	0.048	0.090
45	3.44	4.44	4.36	38.6	4.84	0.026	0.061
Mean	3.417	4.246	4.302	36.86	5.639	0.0544	0.0781
SD	0.163	0.350	0.434	1.85	0.484	0.0389	0.0236
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767117

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
71	3.31	4.11	4.02	38.2	5.38	0.039	0.134
72	3.45	3.85	4.25	35.8	4.91	0.042	0.098
73	3.46	3.98	4.20	35.7	4.69	0.055	0.120
74	3.36	4.05	4.08	35.5	5.19	0.071	0.116
75	3.48	4.81	4.07	36.4	6.66	0.068	0.079
Mean	3.414	4.161	4.121	36.34	5.367	0.0550	0.1094
SD	0.072	0.376	0.097	1.10	0.771	0.0145	0.0212
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767118

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
101	3.45	4.48	4.48	37.8	5.78	0.036	0.044
102	3.32	4.07	4.26	38.0	5.73	0.035	0.070
103	3.28	4.16	4.16	41.0	5.45	0.058	0.122
104	3.38	3.85	3.69	35.6	5.71	0.031	0.041
105	3.28	4.09	4.34	37.5	5.42	0.049	0.069
Mean	3.341	4.130	4.186	37.98	5.618	0.0418	0.0693
SD	0.073	0.226	0.298	1.92	0.169	0.0112	0.0322
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767119

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
131	3.14	3.54	3.56	33.7	4.63	0.040	0.116
132	3.28	3.87	4.16	37.4	5.20	0.045	0.115
133	3.48	4.34	4.62	35.4	4.81	0.055	0.146
134	3.68	4.32	4.65	36.3	5.29	0.032	0.080
135	3.24	4.39	4.57	35.9	6.19	0.058	0.152
Mean	3.364	4.092	4.312	35.73	5.226	0.0464	0.1217
SD	0.216	0.373	0.462	1.33	0.606	0.0107	0.0290
N	5	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights						
	Heart (g/kg b.w.)	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
191	3.81	4.26	4.54	34.5	7.40	0.056	0.115
192	3.08	4.03	4.21	33.7	5.58	0.049	0.149
193	3.48	3.95	4.14	37.7	5.26	0.037	0.090
194	3.30	3.86	3.92	31.2	4.75	0.045	0.062
195	3.76	4.27	4.42	35.3	6.54	0.049	0.066
Mean	3.486	4.073	4.247	34.46	5.905	0.0469	0.0966
SD	0.306	0.184	0.242	2.39	1.059	0.0071	0.0361
N	5	5	5	5	5	5	5

FDA-CBER-2021-5683-0767121

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
11	0.031	3.937	2.12	1.39	0.058
12	0.034	3.879	2.14	1.19	0.026
13	0.034	3.000	2.19	1.37	0.025
14	0.028	3.131	2.29	1.90	0.025
15	0.034	2.776	1.82	0.94	0.062
Mean	0.0323	3.3446	2.112	1.357	0.0389
SD	0.0027	0.5299	0.176	0.356	0.0189
N	5	5	5	5	5

FDA-CBER-2021-5683-0767122

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
41	0.039	3.126	2.08	1.13	0.031
42	0.042	4.182	2.50	1.74	0.048
43	0.024	3.357	2.33	0.77	0.041
44	0.034	2.424	2.36	1.56	0.026
45	0.024	3.506	2.46	1.16	0.032
Mean	0.0328	3.3192	2.346	1.273	0.0356
SD	0.0086	0.6362	0.163	0.385	0.0086
N	5	5	5	5	5

FDA-CBER-2021-5683-0767123

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
71	0.029	3.119	2.70	1.10	0.032
72	0.032	1.729	2.42	1.06	0.027
73	0.038	2.701	1.96	0.90	0.025
74	0.031	3.090	2.20	1.35	0.036
75	0.034	3.408	2.33	1.33	0.079
Mean	0.0328	2.8093	2.322	1.148	0.0395
SD	0.0034	0.6543	0.273	0.192	0.0225
N	5	5	5	5	5

FDA-CBER-2021-5683-0767124

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
101	0.036	3.500	2.22	1.14	0.044
102	0.037	4.566	2.19	1.34	0.059
103	0.033	1.668	2.24	1.17	0.038
104	0.026	2.607	2.32	1.03	0.018
105	0.037	3.793	1.97	1.33	0.030
Mean	0.0339	3.2267	2.191	1.203	0.0377
SD	0.0048	1.1184	0.132	0.131	0.0154
N	5	5	5	5	5

FDA-CBER-2021-5683-0767125

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
131	0.033	3.013	2.49	0.71	0.040
132	0.040	2.972	2.21	0.93	0.048
133	0.039	4.176	2.38	1.46	0.036
134	0.037	3.777	2.46	1.37	0.027
135	0.037	2.826	2.07	1.30	0.043
Mean	0.0373	3.3528	2.324	1.156	0.0388
SD	0.0025	0.5910	0.177	0.319	0.0078
N	5	5	5	5	5

FDA-CBER-2021-5683-0767126

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights				
	Pituitary (g/kg b.w.)	Prostate Gland (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
191	0.036	2.822	2.35	1.20	0.034
192	0.028	3.757	1.95	1.00	0.028
193	0.034	3.083	1.92	1.36	0.032
194	0.033	2.845	2.52	1.49	0.033
195	0.036	1.625	2.68	1.12	0.031
Mean	0.0334	2.8265	2.288	1.236	0.0314
SD	0.0032	0.7708	0.339	0.191	0.0021
N	5	5	5	5	5

FDA-CBER-2021-5683-0767127

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
26	0.272	0.272	7.37	0.218	0.276	4.16
27	0.211	0.221	7.04	0.269	0.352	3.41
28	0.229	0.212	6.70	0.174	0.188	3.59
29	0.214	0.210	7.45	0.258	0.254	4.00
30	0.201	0.201	8.07	0.224	0.256	3.86
Mean	0.2252	0.2232	7.326	0.2286	0.2651	3.804
SD	0.0279	0.0281	0.511	0.0372	0.0589	0.302
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0767128

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
56	0.193	0.173	7.40	0.310	0.286	3.90
57	0.171	0.130	7.59	0.166	0.179	3.41
58	0.167	0.156	6.89	0.192	0.189	3.95
59	0.210	0.225	7.66	0.217	0.252	3.58
60	0.192	0.188	7.21	0.228	0.385	3.69
Mean	0.1865	0.1744	7.351	0.2228	0.2578	3.707
SD	0.0177	0.0356	0.312	0.0542	0.0836	0.225
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
86	0.185	0.172	7.89	0.185	0.172	3.86
87	0.206	0.190	7.27	0.327	0.316	3.62
88	0.151	0.158	6.76	0.225	0.215	3.49
89	0.150	0.146	7.53	0.255	0.251	4.13
90	0.178	0.183	7.87	0.161	0.257	3.70
Mean	0.1739	0.1699	7.465	0.2307	0.2421	3.758
SD	0.0236	0.0180	0.470	0.0651	0.0534	0.249
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
116	0.206	0.199	7.44	0.230	0.269	3.78
117	0.166	0.174	7.30	0.217	0.268	3.67
118	0.161	0.150	7.10	0.358	0.304	3.37
119	0.205	0.170	7.46	0.205	0.185	4.10
120	0.184	0.152	7.25	0.204	0.180	3.81
Mean	0.1844	0.1689	7.309	0.2429	0.2413	3.743
SD	0.0212	0.0196	0.148	0.0654	0.0552	0.264
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
146	0.188	0.193	8.04	0.281	0.285	3.77
147	0.195	0.199	8.08	0.299	0.295	5.62
148	0.226	0.218	8.31	0.251	0.255	4.07
149	0.187	0.194	7.25	0.223	0.312	3.98
150	0.206	0.186	7.44	0.264	0.248	3.99
Mean	0.2004	0.1979	7.825	0.2633	0.2790	4.287
SD	0.0162	0.0121	0.453	0.0290	0.0270	0.751
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Adren. Gland (left) (g/kg b.w.)	Adren. Gland (right) (g/kg b.w.)	Brain (g/kg b.w.)	Ovary (left) (g/kg b.w.)	Ovary (right) (g/kg b.w.)	Heart (g/kg b.w.)
206	0.237	0.229	7.70	0.212	0.216	4.06
207	0.198	0.202	7.52	0.186	0.238	4.08
208	0.159	0.193	7.88	0.226	0.193	3.56
209	0.249	0.253	7.92	0.178	0.191	4.02
210	0.168	0.164	7.15	0.241	0.260	4.05
Mean	0.2022	0.2081	7.633	0.2086	0.2195	3.956
SD	0.0400	0.0340	0.315	0.0264	0.0298	0.222
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
26	4.28	4.61	42.0	6.30	0.062	0.107
27	4.21	4.65	38.5	6.10	0.098	0.098
28	3.96	4.20	36.2	6.05	0.051	0.062
29	3.68	3.76	36.1	5.74	0.079	0.190
30	4.09	4.17	38.2	5.71	0.071	0.209
Mean	4.047	4.280	38.19	5.980	0.0722	0.1331
SD	0.235	0.363	2.39	0.249	0.0178	0.0632
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
56	3.90	3.90	35.4	6.92	0.113	0.169
57	4.55	4.55	39.0	5.16	0.065	0.183
58	3.95	3.88	41.7	6.78	0.065	0.141
59	3.85	3.96	36.2	5.87	0.038	0.088
60	4.05	4.53	38.1	6.05	0.072	0.156
Mean	4.060	4.164	38.07	6.155	0.0706	0.1474
SD	0.282	0.342	2.48	0.719	0.0269	0.0367
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
86	3.73	3.86	31.9	5.29	0.055	0.126
87	4.38	4.53	35.0	5.52	0.065	0.202
88	3.91	4.12	34.9	4.93	0.081	0.158
89	4.29	4.70	34.8	6.36	0.089	0.105
90	3.61	3.74	33.5	5.61	0.048	0.065
Mean	3.985	4.190	34.02	5.541	0.0674	0.1313
SD	0.339	0.415	1.34	0.528	0.0174	0.0519
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
116	3.86	4.01	34.7	5.26	0.062	0.148
117	3.95	4.26	33.1	4.78	0.039	0.118
118	3.88	4.13	36.6	4.79	0.088	0.190
119	4.33	4.40	35.2	6.26	0.097	0.201
120	4.33	4.21	37.3	4.81	0.072	0.244
Mean	4.067	4.204	35.36	5.178	0.0717	0.1804
SD	0.240	0.147	1.62	0.637	0.0224	0.0488
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0767137

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
146	3.73	3.94	35.6	5.78	0.235	0.134
147	4.98	5.34	41.4	6.21	0.072	0.151
148	3.99	4.32	38.7	5.80	0.070	0.140
149	4.02	4.24	40.6	6.39	0.079	0.197
150	4.73	4.92	40.3	6.86	0.074	0.120
Mean	4.289	4.550	39.31	6.208	0.1057	0.1486
SD	0.536	0.568	2.31	0.451	0.0721	0.0295
N	5	5	5	5	5	5

FDA-CBER-2021-5683-0767138

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights					
	Kidney (left) (g/kg b.w.)	Kidney (right) (g/kg b.w.)	Liver (g/kg b.w.)	Lungs (g/kg b.w.)	Lymph node (cerv.) (g/kg b.w.)	Lymph node (mesent.) (g/kg b.w.)
206	4.10	4.40	36.4	5.80	0.085	0.216
207	4.32	4.45	38.0	5.70	0.044	0.210
208	3.56	4.27	34.8	5.53	0.042	0.059
209	5.10	5.23	41.1	5.72	0.095	0.104
210	4.20	4.28	39.7	5.88	0.042	0.103
Mean	4.259	4.525	37.99	5.727	0.0617	0.1383
SD	0.554	0.399	2.52	0.132	0.0262	0.0706
N	5	5	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
26	0.066	3.17	2.55	0.062
27	0.062	2.25	2.11	0.047
28	0.065	2.94	1.78	0.048
29	0.079	2.46	1.82	0.071
30	0.059	2.72	1.46	0.071
Mean	0.0662	2.706	1.943	0.0598
SD	0.0078	0.367	0.411	0.0118
N	5	5	5	5

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
56	0.072	2.70	1.53	0.076
57	0.061	2.23	1.62	0.049
58	0.058	2.83	1.85	0.051
59	0.065	2.13	1.87	0.072
60	0.072	2.64	1.32	0.040
Mean	0.0657	2.507	1.638	0.0577
SD	0.0065	0.305	0.229	0.0159
N	5	5	5	5

FDA-CBER-2021-5683-0767141

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
86	0.046	2.47	1.38	0.046
87	0.065	2.25	2.51	0.061
88	0.060	2.22	1.55	0.035
89	0.057	2.55	1.66	0.032
90	0.052	2.52	1.78	0.061
Mean	0.0559	2.403	1.778	0.0471
SD	0.0071	0.158	0.436	0.0136
N	5	5	5	5

FDA-CBER-2021-5683-0767142

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
116	0.055	2.14	1.48	0.047
117	0.039	2.17	1.50	0.036
118	0.062	2.56	1.90	0.055
119	0.062	2.20	1.58	0.054
120	0.068	2.32	1.28	0.056
Mean	0.0572	2.280	1.550	0.0495
SD	0.0110	0.171	0.226	0.0086
N	5	5	5	5

FDA-CBER-2021-5683-0767143

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
146	0.050	2.81	1.68	0.046
147	0.072	3.15	1.67	0.040
148	0.074	2.67	1.89	0.053
149	0.050	3.12	2.26	0.047
150	0.062	2.68	2.02	0.035
Mean	0.0616	2.885	1.903	0.0442
SD	0.0113	0.235	0.248	0.0071
N	5	5	5	5

FDA-CBER-2021-5683-0767144

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TABLE 14-2 Relative Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Relative Organ Weights			
	Pituitary (g/kg b.w.)	Spleen (g/kg b.w.)	Thymus (g/kg b.w.)	Thyroid/Par. (left) (g/kg b.w.)
206	0.055	2.79	1.86	0.051
207	0.081	2.75	1.58	0.061
208	0.071	2.35	1.09	0.034
209	0.062	3.03	1.95	0.033
210	0.061	2.83	1.72	0.038
Mean	0.0661	2.749	1.639	0.0433
SD	0.0101	0.249	0.339	0.0120
N	5	5	5	5

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0399	0.0389	1.962	0.459	0.468	1.750	1.777
	SD	0.0044	0.0047	0.082	0.071	0.068	0.117	0.165
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	1.090	1.351	1.343	11.03	1.702	0.0173	0.0329
	SD	0.117	0.104	0.115	0.78	0.154	0.0030	0.0116
	N	10	10	10	10	10	10	10
		-	-	-	-	-	-	-

FDA-CBER-2021-5683-0767147

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0101	0.7786	1.024	0.465	0.0110
	SD	0.0013	0.1757	0.150	0.110	0.0032
	N	10	10	10	10	10
		-	-	-	-	-

FDA-CBER-2021-5683-0767148

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a1]	Brain (g) [a1]	Epididymis (left) (g) [a2]	Epididymis (right) (g) [a2]	Testis (left) (g) [a]	Testis (right) (g) [a]
Group 1: Control	Mean	0.0381	0.0353	2.004	0.457	0.419	1.797	1.776
	SD	0.0050	0.0051	0.065	0.073	0.036	0.121	0.113
	N	10	10	10	10	10	10	10
	%Diff	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0415	0.0408	1.950	0.449	0.439	1.741	1.756
	SD	0.0059	0.0076	0.063	0.041	0.037	0.074	0.091
	N	10	10	10	10	10	10	10
	%Diff	8.9	15.6	-2.7	-1.8	4.8	-3.1	-1.1
Group 3: 10 µg/ animal BNT162a1	Mean	0.0406	0.0413	1.978	0.577**	0.524**	1.870	1.864
	SD	0.0069	0.0064	0.085	0.100	0.099	0.163	0.172
	N	10	10	10	10	10	10	10
	%Diff	6.6	17.0	-1.3	26.3	25.1	4.1	5.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.0418	0.0392	1.961	0.490	0.462	1.785	1.766
	SD	0.0047	0.0071	0.061	0.054	0.053	0.111	0.118
	N	10	10	10	10	10	10	10
	%Diff	9.7	11.0	-2.1	7.2	10.3	-0.7	-0.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)
[a2] - Anova & Dunnett(Log): ** = $p \leq 0.01$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Epididymis (left) (g) [a]	Epididymis (right) (g) [a]	Testis (left) (g) [a]	Testis (right) (g) [a]
Group 5:	Mean	0.0427	0.0425	1.977	0.533	0.539**	1.840	1.801
100 µg/	SD	0.0084	0.0078	0.100	0.067	0.080	0.185	0.130
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	12.1	20.4	-1.3	16.6	28.6	2.4	1.4
Group 7:	Mean	0.0430	0.0373	1.944	0.554*	0.514*	1.843	1.818
100 µg/	SD	0.0072	0.0114	0.034	0.109	0.097	0.136	0.143
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	12.9	5.7	-3.0	21.2	22.7	2.6	2.4

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a1]	Kidney (right) (g) [a1]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a2]
Group 1: Control	Mean	1.140	1.426	1.479	13.02	1.936	0.0209	0.0330
	SD	0.050	0.086	0.110	0.54	0.504	0.0101	0.0163
	N	10	10	10	10	10	10	10
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.096	1.309	1.334	10.58**	1.853	0.0198	0.0387
	SD	0.182	0.140	0.139	1.09	0.270	0.0028	0.0165
	N	10	10	10	10	10	10	10
	%Diff	-3.9	-8.2	-9.8	-18.7	-4.3	-5.3	17.3
Group 3: 10 µg/ animal BNT162a1	Mean	1.164	1.430	1.461	12.78	2.019	0.0188	0.0399
	SD	0.107	0.090	0.120	1.05	0.232	0.0036	0.0200
	N	10	10	10	10	10	10	10
	%Diff	2.1	0.3	-1.2	-1.8	4.3	-10.0	20.9
Group 4: 30 µg/ animal BNT162b1	Mean	1.095	1.404	1.418	11.72**	1.787	0.0230	0.0334
	SD	0.088	0.077	0.066	0.83	0.170	0.0212	0.0188
	N	10	10	10	10	10	10	10
	%Diff	-3.9	-1.5	-4.1	-10.0	-7.7	10.0	1.2

[a] - Anova & Dunnett(Rank): ** = $p \leq 0.01$
[a1] - Anova & Dunnett
[a2] - Anova & Dunnett(Log)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5:	Mean	1.167	1.483	1.466	13.18	1.912	0.0187	0.0440
100 µg/	SD	0.168	0.150	0.167	1.86	0.230	0.0076	0.0214
animal	N	10	10	10	10	10	10	10
BNT162b1	%Diff	2.4	4.0	-0.9	1.2	-1.2	-10.5	33.3
Group 7:	Mean	1.135	1.390	1.431	12.16	1.877	0.0157	0.0494
100 µg/	SD	0.122	0.093	0.085	1.09	0.232	0.0044	0.0259
animal	N	10	10	10	10	10	10	10
BNT162b2	%Diff	-0.4	-2.5	-3.2	-6.6	-3.0	-24.9	49.7

[a] - Anova & Dunnett

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a1]	Thyroid/Par. (left) (g) [a]
Group 1: Control	Mean	0.0128	0.9274	0.838	0.538	0.0131
	SD	0.0016	0.1703	0.124	0.101	0.0028
	N	10	10	10	10	10
		-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0123	0.7886	0.976	0.463	0.0138
	SD	0.0023	0.2164	0.131	0.099	0.0019
	N	10	10	10	10	10
	%Diff	-3.9	-15.0	16.5	-13.9	5.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.0130	0.8776	1.079**	0.527	0.0124
	SD	0.0020	0.1862	0.149	0.111	0.0034
	N	10	10	10	10	10
	%Diff	1.6	-5.4	28.8	-2.0	-5.3
Group 4: 30 µg/ animal BNT162b1	Mean	0.0126	0.8465	0.951	0.468	0.0134
	SD	0.0023	0.1704	0.109	0.103	0.0022
	N	10	10	10	10	10
	%Diff	-1.6	-8.7	13.5	-13.0	2.3

[a] - Anova & Dunnett: ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Rank)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5:	Mean	0.0119	0.7897	1.030**	0.435	0.0105
100 µg/	SD	0.0027	0.2321	0.145	0.096	0.0025
animal	N	10	9	10	10	10
BNT162b1	%Diff	-7.0	-14.9	22.9	-19.1	-19.8
Group 7:	Mean	0.0113	0.8130	1.049**	0.388**	0.0109
100 µg/	SD	0.0013	0.2047	0.116	0.201	0.0028
animal	N	10	10	10	10	10
BNT162b2	%Diff	-11.7	-12.3	25.2	-27.9	-16.8

[a] - Anova & Dunnett: ** = $p \leq 0.01$

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0370	0.0364	2.022	0.648	0.684	1.888	2.034
	SD	0.0064	0.0051	0.104	0.042	0.030	0.087	0.312
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	1.280	1.544	1.596	13.12	2.244	0.0182	0.0414
	SD	0.195	0.111	0.187	1.27	0.522	0.0064	0.0161
	N	5	5	5	5	5	5	5
		-	-	-	-	-	-	-

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0128	1.0128	0.826	0.408	0.0148
	SD	0.0023	0.1061	0.148	0.071	0.0050
	N	5	5	5	5	5
		-	-	-	-	-

FDA-CBER-2021-5683-0767157

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Epididymis (left) (g) [a]	Epididymis (right) (g) [a1]	Testis (left) (g) [a1]	Testis (right) (g) [a1]
Group 1: Control	Mean	0.0382	0.0384	2.076	0.716	0.662	2.108	2.332
	SD	0.0067	0.0063	0.070	0.080	0.055	0.282	0.756
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0452*	0.0438	1.996	0.676	0.664	1.888	1.928
	SD	0.0030	0.0075	0.049	0.090	0.070	0.065	0.083
	N	5	5	5	5	5	5	4
	%Diff	18.3	14.1	-3.9	-5.6	0.3	-10.4	-17.3
Group 3: 10 µg/ animal BNT162a1	Mean	0.0434	0.0424	2.118	0.798	0.808*	2.032	2.028
	SD	0.0032	0.0069	0.103	0.073	0.098	0.269	0.261
	N	5	5	5	5	5	5	5
	%Diff	13.6	10.4	2.0	11.5	22.1	-3.6	-13.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.0346	0.0344	1.996	0.660	0.608	2.080	2.258
	SD	0.0030	0.0061	0.134	0.111	0.085	0.457	0.886
	N	5	5	5	5	5	5	5
	%Diff	-9.4	-10.4	-3.9	-7.8	-8.2	-1.3	-3.2

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Rank): * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Epididymis (left) (g) [a]	Epididymis (right) (g) [a]	Testis (left) (g) [a]	Testis (right) (g) [a]
Group 5:	Mean	0.0394	0.0388	2.086	0.808	0.776*	1.954	1.966
100 µg/	SD	0.0032	0.0019	0.101	0.083	0.038	0.227	0.222
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	3.1	1.0	0.5	12.8	17.2	-7.3	-15.7
Group 7:	Mean	0.0348	0.0366	1.998	0.710	0.704	1.966	1.964
100 µg/	SD	0.0041	0.0068	0.090	0.106	0.099	0.106	0.056
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	-8.9	-4.7	-3.8	-0.8	6.3	-6.7	-15.8

[a] - Anova & Dunnett: * = p ≤ 0.05

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a1]	Lymph node (mesent.) (g) [a]
Group 1: Control	Mean	1.276	1.700	1.802	13.64	2.046	0.0194	0.0252
	SD	0.065	0.106	0.050	1.48	0.182	0.0057	0.0050
	N	5	5	5	5	5	5	5
	-	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.284	1.594	1.614	13.88	2.122	0.0200	0.0290
	SD	0.034	0.078	0.101	1.04	0.205	0.0134	0.0074
	N	5	5	5	5	5	5	5
	%Diff	0.6	-6.2	-10.4	1.8	3.7	3.1	15.1
Group 3: 10 µg/ animal BNT162a1	Mean	1.378	1.688	1.662	14.68	2.184	0.0224	0.0440*
	SD	0.107	0.276	0.102	1.33	0.478	0.0071	0.0083
	N	5	5	5	5	5	5	5
	%Diff	8.0	-0.7	-7.8	7.6	6.7	15.5	74.6
Group 4: 30 µg/ animal BNT162b1	Mean	1.320	1.632	1.654	15.06	2.218	0.0168	0.0282
	SD	0.098	0.154	0.172	2.02	0.145	0.0061	0.0160
	N	5	5	5	5	5	5	5
	%Diff	3.4	-4.0	-8.2	10.4	8.4	-13.4	11.9

[a] - Anova & Dunnett: * = p ≤ 0.05
[a1] - Anova & Dunnett(Log)

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Three LNP-Formulated
RNA Platforms encoding for Viral Proteins

TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights						
		Heart (g) [a]	Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5:	Mean	1.302	1.580	1.664	13.82	2.020	0.0178	0.0468*
100 µg/	SD	0.107	0.118	0.144	0.69	0.222	0.0034	0.0098
animal	N	5	5	5	5	5	5	5
BNT162b1	%Diff	2.0	-7.1	-7.7	1.3	-1.3	-8.2	85.7
Group 7:	Mean	1.314	1.536	1.602	13.04	2.226	0.0176	0.0366
100 µg/	SD	0.154	0.143	0.164	1.85	0.413	0.0024	0.0144
animal	N	5	5	5	5	5	5	5
BNT162b2	%Diff	3.0	-9.6	-11.1	-4.4	8.8	-9.3	45.2

[a] - Anova & Dunnett: * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a1]
Group 1: Control	Mean	0.0126	1.2958	0.818	0.522	0.0152
	SD	0.0017	0.1952	0.054	0.112	0.0077
	N	5	5	5	5	5
	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0122	1.2478	0.884	0.474	0.0134
	SD	0.0026	0.2328	0.087	0.128	0.0034
	N	5	5	5	5	5
	%Diff	-3.2	-3.7	8.1	-9.2	-11.8
Group 3: 10 µg/ animal BNT162a1	Mean	0.0132	1.1472	0.940	0.468	0.0164
	SD	0.0013	0.3332	0.147	0.111	0.0107
	N	5	5	5	5	5
	%Diff	4.8	-11.5	14.9	-10.3	7.9
Group 4: 30 µg/ animal BNT162b1	Mean	0.0134	1.2532	0.866	0.476	0.0148
	SD	0.0021	0.3862	0.090	0.067	0.0056
	N	5	5	5	5	5
	%Diff	6.3	-3.3	5.9	-8.8	-2.6

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Male		Absolute Organ Weights				
		Pituitary (g) [a]	Prostate Gland (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5:	Mean	0.0144	1.2952	0.902	0.444	0.0150
100 µg/	SD	0.0005	0.2148	0.113	0.112	0.0029
animal	N	5	5	5	5	5
BNT162b1	%Diff	14.3	0.0	10.3	-14.9	-1.3
Group 7:	Mean	0.0126	1.0658	0.858	0.464	0.0118
100 µg/	SD	0.0015	0.3150	0.113	0.067	0.0008
animal	N	5	5	5	5	5
BNT162b2	%Diff	0.0	-17.7	4.9	-11.1	-22.4

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767163

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0440	0.0411	1.777	0.0438	0.0459	0.781
	SD	0.0048	0.0034	0.074	0.0116	0.0099	0.097
	N	10	10	10	10	10	10
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767164

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.884	0.923	8.08	1.452	0.0142	0.0223
	SD	0.051	0.064	0.64	0.156	0.0054	0.0098
	N	10	10	10	10	10	10
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767165

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 10 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0115	0.762	0.355	0.0093
	SD	0.0019	0.129	0.085	0.0018
	N	10	10	10	10
		-	-	-	-

FDA-CBER-2021-5683-0767166

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a1]	Heart (g) [a1]
Group 1: Control	Mean	0.0453	0.0437	1.859	0.0539	0.0581	0.914
	SD	0.0090	0.0079	0.059	0.0156	0.0091	0.041
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0465	0.0463	1.839	0.0556	0.0538	0.863
	SD	0.0077	0.0045	0.091	0.0132	0.0189	0.059
	N	10	10	10	10	10	10
	%Diff	2.6	5.9	-1.1	3.2	-7.4	-5.6
Group 3: 10 µg/ animal BNT162a1	Mean	0.0454	0.0456	1.846	0.0578	0.0606	0.862
	SD	0.0083	0.0073	0.078	0.0108	0.0111	0.109
	N	10	10	10	10	10	10
	%Diff	0.2	4.3	-0.7	7.2	4.3	-5.7
Group 4: 30 µg/ animal BNT162b1	Mean	0.0455	0.0454	1.876	0.0559	0.0534	0.952
	SD	0.0050	0.0050	0.077	0.0067	0.0044	0.105
	N	10	10	10	10	10	10
	%Diff	0.4	3.9	0.9	3.7	-8.1	4.2

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank)

FDA-CBER-2021-5683-0767167

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a]	Heart (g) [a]
Group 5:	Mean	0.0516	0.0506	1.866	0.0545	0.0589	0.879
100 µg/	SD	0.0059	0.0074	0.087	0.0075	0.0116	0.073
animal	N	10	10	10	10	10	10
BNT162b1	%Diff	13.9	15.8	0.4	1.1	1.4	-3.8
Group 7:	Mean	0.0494	0.0490	1.868	0.0492	0.0564	0.866
100 µg/	SD	0.0070	0.0066	0.072	0.0106	0.0114	0.065
animal	N	10	10	10	10	10	10
BNT162b2	%Diff	9.1	12.1	0.5	-8.7	-2.9	-5.3

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767168

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a1]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a2]
Group 1: Control	Mean	0.938	0.989	8.35	1.333	0.0161	0.0339
	SD	0.077	0.076	0.61	0.096	0.0059	0.0175
	N	10	10	10	10	10	10
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.991	1.019	9.12	1.489	0.0182	0.0280
	SD	0.046	0.038	0.34	0.174	0.0061	0.0128
	N	10	10	10	10	10	10
	%Diff	5.7	3.0	9.2	11.7	13.0	-17.4
Group 3: 10 µg/ animal BNT162a1	Mean	0.983	0.988	8.82	1.494	0.0190	0.0390
	SD	0.099	0.089	1.01	0.154	0.0050	0.0098
	N	10	10	10	10	10	10
	%Diff	4.8	-0.1	5.6	12.1	18.0	15.0
Group 4: 30 µg/ animal BNT162b1	Mean	0.998	1.027	9.67**	1.565	0.0180	0.0325
	SD	0.077	0.078	1.25	0.168	0.0041	0.0223
	N	10	10	10	10	10	10
	%Diff	6.4	3.8	15.8	17.4	11.8	-4.1

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Rank): ** = p ≤ 0.01
[a2] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767169

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.044	1.079	10.07**	1.494	0.0173	0.0429
	SD	0.101	0.095	1.25	0.207	0.0055	0.0165
	N	10	10	10	10	10	10
	%Diff	11.3	9.1	20.6	12.1	7.5	26.5
Group 7: 100 µg/ animal BNT162b2	Mean	1.009	1.057	9.95**	1.524	0.0167	0.0371
	SD	0.075	0.088	0.69	0.170	0.0076	0.0244
	N	10	10	10	10	10	10
	%Diff	7.6	6.9	19.2	14.3	3.7	9.4

[a] - Anova & Dunnett: ** = $p \leq 0.01$

FDA-CBER-2021-5683-0767170

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a1]
Group 1: Control	Mean	0.0150	0.595	0.456	0.0129
	SD	0.0022	0.135	0.089	0.0028
	N	10	10	10	10
	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0129	0.941**	0.435	0.0121
	SD	0.0026	0.146	0.099	0.0039
	N	10	10	10	10
	%Diff	-14.0	58.2	-4.6	-6.2
Group 3: 10 µg/ animal BNT162a1	Mean	0.0149	0.734	0.487	0.0113
	SD	0.0021	0.051	0.105	0.0027
	N	10	10	10	10
	%Diff	-0.7	23.4	6.8	-12.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0140	0.777*	0.457	0.0094
	SD	0.0029	0.135	0.139	0.0013
	N	10	10	10	10
	%Diff	-6.7	30.6	0.2	-27.1

[a] - Anova & Dunnett: * = p ≤ 0.05; ** = p ≤ 0.01
[a1] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767171

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 17 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	0.0143	0.921**	0.387	0.0094
	SD	0.0022	0.151	0.081	0.0035
	N	10	9	10	10
	%Diff	-4.7	54.8	-15.1	-27.1
Group 7: 100 µg/ animal BNT162b2	Mean	0.0143	0.957**	0.390	0.0109
	SD	0.0023	0.130	0.108	0.0036
	N	10	10	10	10
	%Diff	-4.7	60.8	-14.5	-15.5

[a] - Anova & Dunnett: ** = $p \leq 0.01$

FDA-CBER-2021-5683-0767172

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0476	0.0462	1.850	0.0626	0.0636	0.902
	SD	0.0088	0.0058	0.090	0.0129	0.0166	0.091
	N	5	5	5	5	5	5
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767173

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	1.002	1.026	8.52	1.344	0.0142	0.0404
	SD	0.141	0.115	0.81	0.166	0.0044	0.0105
	N	5	5	5	5	5	5
		-	-	-	-	-	-

FDA-CBER-2021-5683-0767174

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 31 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
Group 6: 30 µg/ animal BNT162c1	Mean	0.0152	0.564	0.428	0.0104
	SD	0.0028	0.084	0.060	0.0011
	N	5	5	5	5
		-	-	-	-

FDA-CBER-2021-5683-0767175

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a]	Heart (g) [a1]
Group 1: Control	Mean	0.0592	0.0586	1.924	0.0600	0.0696	0.998
	SD	0.0071	0.0063	0.097	0.0095	0.0160	0.041
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0478*	0.0448**	1.884	0.0570	0.0658	0.952
	SD	0.0047	0.0097	0.080	0.0130	0.0200	0.091
	N	5	5	5	5	5	5
	%Diff	-19.3	-23.5	-2.1	-5.0	-5.5	-4.6
Group 3: 10 µg/ animal BNT162a1	Mean	0.0438**	0.0428**	1.876	0.0588	0.0612	0.946
	SD	0.0063	0.0052	0.044	0.0192	0.0149	0.066
	N	5	5	5	5	5	5
	%Diff	-26.0	-27.0	-2.5	-2.0	-12.1	-5.2
Group 4: 30 µg/ animal BNT162b1	Mean	0.0476*	0.0436**	1.888	0.0632	0.0626	0.966
	SD	0.0051	0.0048	0.056	0.0197	0.0159	0.056
	N	5	5	5	5	5	5
	%Diff	-19.6	-25.6	-1.9	5.3	-10.1	-3.2

[a] - Anova & Dunnett: * = $p \leq 0.05$; ** = $p \leq 0.01$
[a1] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767176

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Adren. Gland (left) (g) [a]	Adren. Gland (right) (g) [a]	Brain (g) [a]	Ovary (left) (g) [a]	Ovary (right) (g) [a]	Heart (g) [a]
Group 5:	Mean	0.0508	0.0502	1.982	0.0666	0.0710	1.088
100 µg/	SD	0.0039	0.0033	0.057	0.0056	0.0100	0.195
animal	N	5	5	5	5	5	5
BNT162b1	%Diff	-14.2	-14.3	3.0	11.0	2.0	9.0
Group 7:	Mean	0.0494	0.0508	1.868	0.0512	0.0540	0.970
100 µg/	SD	0.0089	0.0070	0.033	0.0078	0.0095	0.078
animal	N	5	5	5	5	5	5
BNT162b2	%Diff	-16.6	-13.3	-2.9	-14.7	-22.4	-2.8

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767177

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a1]	Lymph node (mesent.) (g) [a]
Group 1: Control	Mean	1.066	1.128	10.04	1.576	0.0190	0.0344
	SD	0.097	0.132	0.64	0.143	0.0049	0.0152
	N	5	5	5	5	5	5
	-	-	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	1.040	1.066	9.78	1.582	0.0180	0.0376
	SD	0.062	0.065	1.01	0.227	0.0065	0.0085
	N	5	5	5	5	5	5
	%Diff	-2.4	-5.5	-2.6	0.4	-5.3	9.3
Group 3: 10 µg/ animal BNT162a1	Mean	1.008	1.060	8.60	1.394	0.0172	0.0338
	SD	0.140	0.157	0.98	0.125	0.0053	0.0152
	N	5	5	5	5	5	5
	%Diff	-5.4	-6.0	-14.3	-11.5	-9.5	-1.7
Group 4: 30 µg/ animal BNT162b1	Mean	1.050	1.086	9.14	1.338	0.0186	0.0466
	SD	0.055	0.048	0.59	0.170	0.0061	0.0124
	N	5	5	5	5	5	5
	%Diff	-1.5	-3.7	-9.0	-15.1	-2.1	35.5

[a] - Anova & Dunnett
[a1] - Anova & Dunnett(Log)

FDA-CBER-2021-5683-0767178

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights					
		Kidney (left) (g) [a]	Kidney (right) (g) [a]	Liver (g) [a]	Lungs (g) [a]	Lymph node (cerv.) (g) [a]	Lymph node (mesent.) (g) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	1.090	1.156	10.00	1.580	0.0264	0.0380
	SD	0.156	0.162	1.07	0.191	0.0167	0.0099
	N	5	5	5	5	5	5
	%Diff	2.3	2.5	-0.4	0.3	38.9	10.5
Group 7: 100 µg/ animal BNT162b2	Mean	1.044	1.108	9.32	1.404	0.0150	0.0338
	SD	0.143	0.094	0.88	0.083	0.0060	0.0169
	N	5	5	5	5	5	5
	%Diff	-2.1	-1.8	-7.2	-10.9	-21.1	-1.7

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767179

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 1: Control	Mean	0.0174	0.712	0.510	0.0156
	SD	0.0021	0.103	0.099	0.0023
	N	5	5	5	5
	-	-	-	-	-
Group 2: 30 µg/ animal BNT162a1	Mean	0.0168	0.644	0.422	0.0148
	SD	0.0013	0.094	0.076	0.0041
	N	5	5	5	5
	%Diff	-3.4	-9.6	-17.3	-5.1
Group 3: 10 µg/ animal BNT162a1	Mean	0.0142	0.604	0.450	0.0118
	SD	0.0028	0.024	0.124	0.0032
	N	5	5	5	5
	%Diff	-18.4	-15.2	-11.8	-24.4
Group 4: 30 µg/ animal BNT162b1	Mean	0.0148	0.590	0.402	0.0128
	SD	0.0029	0.063	0.074	0.0024
	N	5	5	5	5
	%Diff	-14.9	-17.1	-21.2	-17.9

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767180

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Day: 38 Relative to Start Date

Sex: Female		Absolute Organ Weights			
		Pituitary (g) [a]	Spleen (g) [a]	Thymus (g) [a]	Thyroid/Par. (left) (g) [a]
Group 5: 100 µg/ animal BNT162b1	Mean	0.0156	0.734	0.486	0.0112
	SD	0.0026	0.093	0.093	0.0018
	N	5	5	5	5
	%Diff	-10.3	3.1	-4.7	-28.2
Group 7: 100 µg/ animal BNT162b2	Mean	0.0162	0.674	0.402	0.0106
	SD	0.0026	0.072	0.085	0.0030
	N	5	5	5	5
	%Diff	-6.9	-5.3	-21.2	-32.1

[a] - Anova & Dunnett

FDA-CBER-2021-5683-0767181

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	3	Male	Epididymis - Left	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	3	Male	Epididymis - Right	**	Anova & Dunnett(Log): ** = p ≤ 0.01
	17	5	Male	Epididymis - Right	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Epididymis - Left	*	Anova & Dunnett: * = p ≤ 0.05
	17	7	Male	Epididymis - Right	*	Anova & Dunnett: * = p ≤ 0.05

FDA-CBER-2021-5683-0767182

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Male	Liver	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	4	Male	Liver	**	Anova & Dunnett(Rank): ** = p ≤ 0.01

FDA-CBER-2021-5683-0767183

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	3	Male	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	5	Male	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Male	Thymus Weight	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Male	Adrenal Wt left	*	Anova & Dunnett: * = p ≤ 0.05
	38	3	Male	Epididymis - Right	*	Anova & Dunnett(Rank): * = p ≤ 0.05
	38	5	Male	Epididymis - Right	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	3	Male	Lymph node (mesent.)	*	Anova & Dunnett: * = p ≤ 0.05
	38	5	Male	Lymph node (mesent.)	*	Anova & Dunnett: * = p ≤ 0.05

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	4	Female	Liver	**	Anova & Dunnett(Rank): ** = p ≤ 0.01
	17	5	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Liver	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	17	2	Female	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	4	Female	Spleen Weight	*	Anova & Dunnett: * = p ≤ 0.05
	17	5	Female	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01
	17	7	Female	Spleen Weight	**	Anova & Dunnett: ** = p ≤ 0.01

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TABLE 15-1 Absolute Organ Weights - Summary Rat

Comments and Markers

Page	Day	Group	Sex	Measurement	Marker	Comment
	38	2	Female	Adrenal Wt left	*	Anova & Dunnett: * = p ≤ 0.05
	38	2	Female	Adrenal Wt right	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	Adrenal Wt left	**	Anova & Dunnett: ** = p ≤ 0.01
	38	3	Female	Adrenal Wt right	**	Anova & Dunnett: ** = p ≤ 0.01
	38	4	Female	Adrenal Wt left	*	Anova & Dunnett: * = p ≤ 0.05
	38	4	Female	Adrenal Wt right	**	Anova & Dunnett: ** = p ≤ 0.01

FDA-CBER-2021-5683-0767189

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
151	0.042	0.038	1.91	0.51	0.54	1.84	2.13
152	0.040	0.043	1.94	0.56	0.51	1.85	1.79
153	0.040	0.042	1.88	0.49	0.57	1.73	1.76
154	0.040	0.038	2.06	0.47	0.45	1.96	1.97
155	0.039	0.044	2.05	0.42	0.40	1.75	1.74
156	0.044	0.041	2.00	0.53	0.52	1.72	1.61
157	0.045	0.044	2.04	0.43	0.48	1.76	1.82
158	0.042	0.036	1.89	0.34	0.35	1.53	1.61
159	0.038	0.032	2.02	0.48	0.44	1.71	1.70
160	0.029	0.031	1.83	0.36	0.42	1.65	1.64
Mean	0.0399	0.0389	1.962	0.459	0.468	1.750	1.777
SD	0.0044	0.0047	0.082	0.071	0.068	0.117	0.165
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
151	1.09	1.25	1.22	11.0	1.66	0.012	0.036
152	1.15	1.58	1.56	11.5	1.86	0.016	0.026
153	0.96	1.38	1.40	9.9	1.62	0.020	0.043
154	1.09	1.42	1.35	11.2	1.90	0.020	0.031
155	1.05	1.36	1.42	11.7	1.97	0.021	0.026
156	1.11	1.35	1.26	11.1	1.60	0.013	0.027
157	1.07	1.37	1.43	12.3	1.57	0.016	0.030
158	1.38	1.33	1.28	10.5	1.71	0.018	0.012
159	1.01	1.26	1.34	11.3	1.52	0.019	0.051
160	0.99	1.21	1.17	9.8	1.61	0.018	0.047
Mean	1.090	1.351	1.343	11.03	1.702	0.0173	0.0329
SD	0.117	0.104	0.115	0.78	0.154	0.0030	0.0116
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
151	0.011	0.742	0.92	0.64	0.016
152	0.012	1.088	1.09	0.54	0.015
153	0.009	0.791	0.89	0.41	0.006
154	0.011	1.072	1.30	0.44	0.009
155	0.011	0.835	1.24	0.66	0.013
156	0.009	0.703	0.88	0.42	0.012
157	0.010	0.656	0.94	0.37	0.008
158	0.008	0.679	0.92	0.40	0.011
159	0.011	0.653	0.97	0.42	0.012
160	0.009	0.567	1.09	0.35	0.008
Mean	0.0101	0.7786	1.024	0.465	0.0110
SD	0.0013	0.1757	0.150	0.110	0.0032
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
166	0.043	0.045	1.74	0.039	0.042	0.88
167	0.041	0.040	1.87	0.040	0.043	0.80
168	0.042	0.039	1.77	0.049	0.062	0.69
169	0.048	0.045	1.83	0.065	0.061	0.75
170	0.035	0.035	1.83	0.044	0.043	1.00
171	0.045	0.039	1.83	0.020	0.028	0.72
172	0.040	0.041	1.68	0.046	0.046	0.78
173	0.049	0.046	1.64	0.054	0.046	0.73
174	0.046	0.040	1.82	0.039	0.040	0.68
175	0.051	0.041	1.76	0.042	0.048	0.78
Mean	0.0440	0.0411	1.777	0.0438	0.0459	0.781
SD	0.0048	0.0034	0.074	0.0116	0.0099	0.097
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
166	0.85	0.96	8.8	1.47	0.005	0.015
167	0.93	0.99	8.2	1.55	0.012	0.020
168	0.88	0.94	7.2	1.10	0.012	0.024
169	0.97	1.00	8.5	1.46	0.024	0.036
170	0.92	0.90	8.3	1.53	0.020	0.039
171	0.82	0.90	7.2	1.48	0.018	0.017
172	0.84	0.80	8.3	1.55	0.011	0.014
173	0.92	0.96	8.9	1.39	0.014	0.015
174	0.82	0.84	7.3	1.32	0.011	0.031
175	0.89	0.94	8.1	1.67	0.015	0.012
Mean	0.884	0.923	8.08	1.452	0.0142	0.0223
SD	0.051	0.064	0.64	0.156	0.0054	0.0098
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 10 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
166	0.012	0.78	0.47	0.006
167	0.011	0.66	0.35	0.008
168	0.009	0.61	0.32	0.009
169	0.015	0.66	0.39	0.012
170	0.013	0.89	0.43	0.009
171	0.012	0.77	0.18	0.011
172	0.009	0.83	0.26	0.010
173	0.010	0.94	0.39	0.011
174	0.013	0.58	0.35	0.009
175	0.011	0.90	0.41	0.008
Mean	0.0115	0.762	0.355	0.0093
SD	0.0019	0.129	0.085	0.0018
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
1	0.034	0.030	1.97	0.58	0.42	1.84	1.85
2	0.040	0.035	1.95	0.45	0.39	2.01	1.92
3	0.044	0.039	2.12	0.55	0.45	1.75	1.73
4	0.035	0.036	1.95	0.40	0.41	1.73	1.60
5	0.034	0.038	1.91	0.36	0.39	1.66	1.68
6	0.037	0.029	2.03	0.39	0.41	1.77	1.81
7	0.035	0.030	2.05	0.45	0.47	1.63	1.65
8	0.049	0.046	2.00	0.53	0.48	1.97	1.93
9	0.039	0.035	2.08	0.41	0.38	1.81	1.84
10	0.034	0.035	1.98	0.45	0.39	1.80	1.75
Mean	0.0381	0.0353	2.004	0.457	0.419	1.797	1.776
SD	0.0050	0.0051	0.065	0.073	0.036	0.121	0.113
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
31	0.040	0.037	1.94	0.44	0.40	1.83	1.77
32	0.046	0.040	1.91	0.46	0.49	1.74	1.73
33	0.055	0.060	2.05	0.49	0.43	1.83	1.87
34	0.045	0.043	1.83	0.48	0.44	1.77	1.80
35	0.036	0.040	1.92	0.49	0.44	1.73	1.72
36	0.039	0.031	2.01	0.44	0.38	1.61	1.57
37	0.039	0.035	1.98	0.37	0.41	1.74	1.82
38	0.035	0.042	2.00	0.48	0.49	1.80	1.87
39	0.041	0.041	1.95	0.39	0.44	1.73	1.72
40	0.039	0.039	1.91	0.45	0.47	1.63	1.69
Mean	0.0415	0.0408	1.950	0.449	0.439	1.741	1.756
SD	0.0059	0.0076	0.063	0.041	0.037	0.074	0.091
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
61	0.038	0.042	1.98	0.64	0.60	2.09	2.13
62	0.038	0.042	1.89	0.43	0.42	1.77	1.77
63	0.038	0.039	1.92	0.77	0.68	2.14	2.07
64	0.035	0.039	1.97	0.58	0.59	1.82	1.84
65	0.040	0.036	1.95	0.52	0.47	1.97	1.96
66	0.037	0.032	2.17	0.60	0.56	1.84	1.76
67	0.046	0.045	2.03	0.68	0.63	1.89	2.00
68	0.033	0.037	1.89	0.54	0.42	1.78	1.68
69	0.044	0.046	1.94	0.49	0.44	1.58	1.60
70	0.057	0.055	2.04	0.52	0.43	1.82	1.83
Mean	0.0406	0.0413	1.978	0.577	0.524	1.870	1.864
SD	0.0069	0.0064	0.085	0.100	0.099	0.163	0.172
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
91	0.034	0.028	1.92	0.47	0.41	1.84	1.79
92	0.039	0.035	2.03	0.47	0.45	1.61	1.63
93	0.038	0.033	1.88	0.50	0.46	1.80	1.72
94	0.041	0.043	1.88	0.38	0.41	1.65	1.63
95	0.048	0.048	1.90	0.51	0.41	1.82	1.81
96	0.047	0.041	2.01	0.54	0.54	1.83	1.80
97	0.042	0.033	2.02	0.49	0.49	1.72	1.66
98	0.048	0.051	1.98	0.53	0.50	1.96	2.00
99	0.039	0.039	2.02	0.57	0.54	1.91	1.89
100	0.042	0.041	1.97	0.44	0.41	1.71	1.73
Mean	0.0418	0.0392	1.961	0.490	0.462	1.785	1.766
SD	0.0047	0.0071	0.061	0.054	0.053	0.111	0.118
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
121	0.030	0.037	2.11	0.71	0.61	2.14	2.09
122	0.033	0.034	1.90	0.48	0.46	1.64	1.71
123	0.051	0.057	1.98	0.48	0.52	2.12	1.86
124	0.033	0.040	2.18	0.51	0.55	1.82	1.84
125	0.053	0.043	2.03	0.52	0.71	1.69	1.73
126	0.046	0.042	1.92	0.54	0.51	1.75	1.69
127	0.052	0.055	1.88	0.54	0.47	1.71	1.72
128	0.042	0.035	1.92	0.49	0.45	2.02	1.91
129	0.041	0.039	1.94	0.52	0.52	1.81	1.80
130	0.046	0.043	1.91	0.54	0.59	1.70	1.66
Mean	0.0427	0.0425	1.977	0.533	0.539	1.840	1.801
SD	0.0084	0.0078	0.100	0.067	0.080	0.185	0.130
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
181	0.039	0.037	1.95	0.53	0.56	1.97	2.00
182	0.032	0.031	1.91	0.44	0.44	1.59	1.64
183	0.040	0.034	1.95	0.53	0.44	1.75	1.75
184	0.050	0.051	1.95	0.44	0.40	1.72	1.68
185	0.049	0.045	1.91	0.53	0.56	1.99	2.00
186	0.040	0.034	1.95	0.51	0.50	1.91	1.77
187	0.045	0.014	1.97	0.51	0.45	1.78	1.72
188	0.043	0.037	1.89	0.61	0.53	1.96	2.01
189	0.036	0.035	2.01	0.63	0.52	1.97	1.89
190	0.056	0.055	1.95	0.81	0.74	1.79	1.72
Mean	0.0430	0.0373	1.944	0.554	0.514	1.843	1.818
SD	0.0072	0.0114	0.034	0.109	0.097	0.136	0.143
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
1	1.15	1.49	1.56	12.5	1.65	0.020	0.033
2	1.07	1.41	1.50	12.8	1.97	0.018	0.042
3	1.20	1.44	1.46	14.2	1.86	0.023	0.064
4	1.09	1.51	1.63	12.5	1.66	0.013	0.021
5	1.08	1.32	1.36	12.5	1.61	0.045	0.020
6	1.18	1.38	1.41	13.5	1.68	0.009	0.011
7	1.15	1.35	1.31	13.1	3.31	0.014	0.031
8	1.21	1.35	1.39	12.8	1.87	0.028	0.034
9	1.11	1.60	1.61	13.3	2.03	0.017	0.021
10	1.16	1.41	1.56	13.0	1.72	0.022	0.053
Mean	1.140	1.426	1.479	13.02	1.936	0.0209	0.0330
SD	0.050	0.086	0.110	0.54	0.504	0.0101	0.0163
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
31	1.07	1.33	1.32	10.3	1.83	0.023	0.067
32	0.94	1.50	1.52	10.9	1.92	0.019	0.058
33	1.21	1.51	1.56	12.5	2.10	0.022	0.036
34	0.98	1.32	1.31	11.2	1.85	0.017	0.022
35	1.27	1.34	1.27	11.6	1.68	0.017	0.046
36	1.02	1.20	1.23	11.1	1.68	0.017	0.030
37	1.00	1.21	1.25	10.1	1.91	0.018	0.017
38	1.51	1.41	1.44	8.9	2.44	0.021	0.053
39	0.95	1.19	1.34	9.4	1.49	0.019	0.031
40	1.01	1.08	1.10	9.8	1.63	0.025	0.027
Mean	1.096	1.309	1.334	10.58	1.853	0.0198	0.0387
SD	0.182	0.140	0.139	1.09	0.270	0.0028	0.0165
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
61	1.16	1.41	1.49	13.1	1.93	0.019	0.035
62	0.96	1.38	1.42	12.6	1.86	0.016	0.053
63	1.16	1.42	1.53	12.3	2.04	0.013	0.025
64	1.13	1.47	1.51	11.5	1.78	0.020	0.045
65	1.19	1.59	1.50	14.6	1.85	0.020	0.053
66	1.29	1.50	1.47	13.1	2.03	0.025	0.029
67	1.16	1.51	1.65	13.1	2.32	0.021	0.038
68	1.04	1.28	1.18	11.0	1.76	0.021	0.017
69	1.32	1.40	1.41	12.6	2.17	0.019	0.020
70	1.23	1.34	1.45	13.9	2.45	0.014	0.084
Mean	1.164	1.430	1.461	12.78	2.019	0.0188	0.0399
SD	0.107	0.090	0.120	1.05	0.232	0.0036	0.0200
N	10	10	10	10	10	10	10

FDA-CBER-2021-5683-0767204

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
91	1.25	1.38	1.40	11.6	2.04	0.023	0.049
92	0.99	1.36	1.41	10.0	1.49	0.013	0.067
93	1.09	1.42	1.27	11.6	1.85	0.016	0.036
94	1.19	1.42	1.51	12.7	1.94	0.009	0.011
95	1.17	1.47	1.45	12.0	1.74	0.012	0.020
96	1.10	1.46	1.49	12.9	1.96	0.082	0.050
97	1.00	1.25	1.45	11.2	1.62	0.018	0.022
98	1.05	1.49	1.39	11.8	1.65	0.017	0.027
99	1.00	1.47	1.42	12.2	1.77	0.019	0.043
100	1.11	1.32	1.39	11.2	1.81	0.021	0.009
Mean	1.095	1.404	1.418	11.72	1.787	0.0230	0.0334
SD	0.088	0.077	0.066	0.83	0.170	0.0212	0.0188
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
121	1.54	1.46	1.48	13.2	1.95	0.019	0.021
122	1.01	1.41	1.31	11.2	2.06	0.008	0.082
123	1.14	1.46	1.44	12.9	1.90	0.010	0.027
124	1.33	1.67	1.75	15.2	2.37	0.019	0.027
125	1.04	1.37	1.35	12.0	1.68	0.022	0.050
126	1.27	1.63	1.63	16.2	2.16	0.034	0.070
127	1.10	1.57	1.41	12.0	1.76	0.026	0.039
128	1.01	1.16	1.19	12.1	1.77	0.020	0.064
129	1.14	1.49	1.47	11.3	1.63	0.015	0.034
130	1.09	1.61	1.63	15.7	1.84	0.014	0.026
Mean	1.167	1.483	1.466	13.18	1.912	0.0187	0.0440
SD	0.168	0.150	0.167	1.86	0.230	0.0076	0.0214
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
181	1.29	1.41	1.47	12.9	1.85	0.014	0.017
182	0.97	1.31	1.39	10.4	1.73	0.017	0.046
183	1.00	1.34	1.42	12.4	1.84	0.012	0.094
184	1.34	1.35	1.37	11.8	1.64	0.018	0.025
185	1.17	1.47	1.42	14.4	2.13	0.023	0.053
186	1.02	1.39	1.43	11.5	1.71	0.022	0.086
187	1.10	1.22	1.27	11.6	2.14	0.015	0.064
188	1.21	1.38	1.44	12.4	1.74	0.009	0.024
189	1.14	1.53	1.59	11.4	1.68	0.015	0.049
190	1.11	1.50	1.51	12.8	2.31	0.012	0.036
Mean	1.135	1.390	1.431	12.16	1.877	0.0157	0.0494
SD	0.122	0.093	0.085	1.09	0.232	0.0044	0.0259
N	10	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
1	0.014	0.628	0.69	0.45	0.013
2	0.012	1.032	0.88	0.58	0.018
3	0.015	0.928	0.82	0.65	0.012
4	0.013	1.120	0.63	0.41	0.013
5	0.010	0.952	0.77	0.48	0.015
6	0.012	0.728	0.96	0.57	0.011
7	0.011	0.907	0.94	0.55	0.008
8	0.013	1.208	1.04	0.53	0.011
9	0.013	0.900	0.84	0.73	0.016
10	0.015	0.871	0.81	0.43	0.014
Mean	0.0128	0.9274	0.838	0.538	0.0131
SD	0.0016	0.1703	0.124	0.101	0.0028
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
31	0.011	0.852	1.13	0.43	0.015
32	0.012	0.641	0.74	0.48	0.014
33	0.012	0.734	1.14	0.64	0.014
34	0.012	0.813	1.09	0.44	0.014
35	0.013	1.341	1.05	0.58	0.011
36	0.017	0.701	0.99	0.48	0.012
37	0.015	0.623	0.91	0.32	0.018
38	0.009	0.607	0.89	0.47	0.014
39	0.011	0.690	0.84	0.32	0.013
40	0.011	0.884	0.98	0.47	0.013
Mean	0.0123	0.7886	0.976	0.463	0.0138
SD	0.0023	0.2164	0.131	0.099	0.0019
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
61	0.014	0.761	1.07	0.41	0.011
62	0.009	0.668	0.90	0.56	0.013
63	0.014	1.085	1.18	0.41	0.013
64	0.012	0.797	1.03	0.43	0.012
65	0.011	0.718	1.00	0.63	0.008
66	0.014	1.081	1.07	0.42	0.011
67	0.016	1.104	1.27	0.58	0.021
68	0.014	0.993	0.83	0.50	0.011
69	0.014	0.952	1.15	0.73	0.013
70	0.012	0.617	1.29	0.60	0.011
Mean	0.0130	0.8776	1.079	0.527	0.0124
SD	0.0020	0.1862	0.149	0.111	0.0034
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
91	0.012	0.782	1.01	0.47	0.015
92	0.014	0.684	0.73	0.40	0.014
93	0.010	1.001	0.93	0.53	0.016
94	0.010	0.831	0.97	0.51	0.011
95	0.016	0.919	0.89	0.62	0.010
96	0.016	0.854	1.12	0.55	0.014
97	0.011	0.825	0.95	0.37	0.011
98	0.012	0.748	1.08	0.55	0.012
99	0.014	1.213	0.95	0.40	0.015
100	0.011	0.608	0.88	0.28	0.016
Mean	0.0126	0.8465	0.951	0.468	0.0134
SD	0.0023	0.1704	0.109	0.103	0.0022
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
121	0.016	0.703	1.22	0.51	0.014
122	0.007	0.541	0.91	0.39	0.009
123	0.011	0.914	1.15	0.48	0.010
124	0.012	1.013	1.02	0.56	0.013
125	0.014	0.708	0.97	0.36	0.012
126	0.014	0.843	1.28	0.40	0.013
127	0.014	1.000	0.83	0.37	0.010
128	0.009	0.358	1.01	0.32	0.007
129	0.011	NT !	0.90	0.36	0.010
130	0.011	1.027	1.01	0.60	0.007
Mean	0.0119	0.7897	1.030	0.435	0.0105
SD	0.0027	0.2321	0.145	0.096	0.0025
N	10	9	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
181	0.013	0.958	1.15	0.27	0.007
182	0.011	0.664	0.86	0.34	0.013
183	0.013	0.976	0.99	0.30	0.007
184	0.012	0.597	1.05	0.39	0.014
185	0.011	1.190	1.22	0.34	0.010
186	0.010	0.781	0.96	0.23	0.013
187	0.011	0.682	0.96	0.26	0.010
188	0.009	0.755	0.99	0.93	0.008
189	0.012	0.978	1.16	0.39	0.014
190	0.011	0.549	1.15	0.43	0.013
Mean	0.0113	0.8130	1.049	0.388	0.0109
SD	0.0013	0.2047	0.116	0.201	0.0028
N	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
16	0.059	0.056	1.95	0.054	0.060	0.91
17	0.047	0.048	1.82	0.086	0.072	0.91
18	0.028	0.031	1.74	0.066	0.068	0.90
19	0.036	0.034	1.88	0.027	0.060	1.00
20	0.042	0.049	1.90	0.052	0.059	0.86
21	0.041	0.037	1.86	0.057	0.044	0.92
22	0.053	0.050	1.83	0.041	0.060	0.95
23	0.049	0.041	1.83	0.051	0.062	0.90
24	0.046	0.044	1.92	0.059	0.044	0.93
25	0.052	0.047	1.86	0.046	0.052	0.86
Mean	0.0453	0.0437	1.859	0.0539	0.0581	0.914
SD	0.0090	0.0079	0.059	0.0156	0.0091	0.041
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
46	0.054	0.051	1.77	0.064	0.090	0.86
47	0.038	0.040	1.87	0.046	0.034	0.90
48	0.051	0.045	1.77	0.062	0.029	0.95
49	0.033	0.050	1.98	0.037	0.040	0.78
50	0.057	0.050	1.83	0.051	0.047	0.82
51	0.050	0.047	1.87	0.040	0.044	0.85
52	0.043	0.037	1.89	0.048	0.053	0.94
53	0.040	0.047	1.85	0.064	0.064	0.89
54	0.048	0.049	1.91	0.079	0.066	0.86
55	0.051	0.047	1.65	0.065	0.071	0.78
Mean	0.0465	0.0463	1.839	0.0556	0.0538	0.863
SD	0.0077	0.0045	0.091	0.0132	0.0189	0.059
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
76	0.039	0.039	1.73	0.070	0.058	0.91
77	0.047	0.047	1.94	0.044	0.046	0.80
78	0.039	0.041	1.73	0.048	0.059	0.77
79	0.064	0.062	1.88	0.055	0.052	0.99
80	0.049	0.039	1.81	0.075	0.058	0.74
81	0.052	0.046	1.90	0.063	0.071	0.87
82	0.047	0.043	1.91	0.068	0.086	1.08
83	0.040	0.041	1.86	0.055	0.060	0.76
84	0.040	0.044	1.78	0.045	0.054	0.88
85	0.037	0.054	1.92	0.055	0.062	0.82
Mean	0.0454	0.0456	1.846	0.0578	0.0606	0.862
SD	0.0083	0.0073	0.078	0.0108	0.0111	0.109
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
106	0.042	0.044	1.81	0.049	0.048	0.94
107	0.050	0.050	1.96	0.061	0.048	0.91
108	0.042	0.040	1.81	0.051	0.056	0.82
109	0.044	0.041	1.99	0.047	0.053	1.19
110	0.049	0.056	1.79	0.051	0.051	0.92
111	0.042	0.043	1.83	0.064	0.059	1.03
112	0.057	0.050	1.84	0.059	0.048	0.96
113	0.045	0.044	1.94	0.067	0.056	0.98
114	0.042	0.044	1.83	0.053	0.059	0.94
115	0.042	0.042	1.96	0.057	0.056	0.83
Mean	0.0455	0.0454	1.876	0.0559	0.0534	0.952
SD	0.0050	0.0050	0.077	0.0067	0.0044	0.105
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
136	0.059	0.054	2.04	0.045	0.045	1.04
137	0.053	0.048	1.82	0.064	0.073	0.77
138	0.050	0.054	1.74	0.056	0.051	0.81
139	0.045	0.041	1.86	0.056	0.055	0.86
140	0.048	0.047	1.84	0.050	0.062	0.91
141	0.050	0.054	1.88	0.053	0.049	0.92
142	0.051	0.045	1.98	0.054	0.069	0.90
143	0.045	0.042	1.82	0.042	0.046	0.86
144	0.051	0.056	1.81	0.065	0.078	0.84
145	0.064	0.065	1.87	0.060	0.061	0.88
Mean	0.0516	0.0506	1.866	0.0545	0.0589	0.879
SD	0.0059	0.0074	0.087	0.0075	0.0116	0.073
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
196	0.040	0.050	1.91	0.044	0.058	0.96
197	0.050	0.047	1.84	0.051	0.044	0.88
198	0.040	0.036	1.75	0.063	0.067	0.84
199	0.060	0.055	1.80	0.048	0.077	0.77
200	0.060	0.059	1.89	0.030	0.050	0.84
201	0.050	0.048	1.96	0.046	0.047	0.87
202	0.053	0.054	1.89	0.057	0.056	0.79
203	0.048	0.052	1.91	0.066	0.060	0.86
204	0.044	0.043	1.78	0.045	0.065	0.98
205	0.049	0.046	1.95	0.042	0.040	0.87
Mean	0.0494	0.0490	1.868	0.0492	0.0564	0.866
SD	0.0070	0.0066	0.072	0.0106	0.0114	0.065
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
16	1.12	1.07	9.6	1.38	0.012	0.021
17	0.90	1.03	8.0	1.25	0.031	0.036
18	0.89	0.93	7.4	1.33	0.014	0.049
19	0.88	0.86	8.9	1.54	0.017	0.018
20	0.86	0.91	7.9	1.38	0.010	0.015
21	0.90	0.99	8.0	1.18	0.015	0.029
22	0.97	0.94	8.3	1.30	0.018	0.044
23	0.91	1.03	8.2	1.28	0.014	0.042
24	0.99	1.09	8.5	1.32	0.018	0.069
25	0.96	1.04	8.7	1.37	0.012	0.016
Mean	0.938	0.989	8.35	1.333	0.0161	0.0339
SD	0.077	0.076	0.61	0.096	0.0059	0.0175
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
46	1.07	1.10	9.5	1.47	0.024	0.039
47	1.00	1.04	9.2	1.63	0.021	0.018
48	0.95	1.01	9.6	1.35	0.008	0.054
49	1.06	1.04	8.5	1.46	0.016	0.017
50	0.99	1.01	8.8	1.64	0.014	0.024
51	0.98	0.97	9.4	1.39	0.011	0.017
52	1.01	1.00	9.0	1.78	0.017	0.018
53	0.97	1.03	9.2	1.15	0.021	0.020
54	0.94	0.97	9.1	1.51	0.028	0.038
55	0.94	1.02	8.9	1.51	0.022	0.035
Mean	0.991	1.019	9.12	1.489	0.0182	0.0280
SD	0.046	0.038	0.34	0.174	0.0061	0.0128
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
76	0.94	0.99	9.3	1.62	0.023	0.041
77	1.06	1.00	9.0	1.64	0.029	0.055
78	0.92	0.93	8.1	1.27	0.020	0.045
79	1.15	1.14	10.1	1.55	0.021	0.027
80	0.92	0.91	7.5	1.28	0.018	0.030
81	1.02	0.96	9.2	1.49	0.011	0.030
82	1.12	1.12	10.3	1.74	0.015	0.054
83	0.95	0.86	7.7	1.45	0.016	0.036
84	0.89	0.94	9.3	1.52	0.021	0.034
85	0.86	1.03	7.7	1.38	0.016	0.038
Mean	0.983	0.988	8.82	1.494	0.0190	0.0390
SD	0.099	0.089	1.01	0.154	0.0050	0.0098
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
106	1.06	1.10	9.7	1.44	0.021	0.054
107	1.01	1.02	8.5	1.53	0.017	0.013
108	0.98	1.00	9.0	1.43	0.011	0.030
109	1.10	1.14	12.0	1.86	0.023	0.024
110	0.91	0.94	9.6	1.32	0.023	0.019
111	1.10	1.14	9.7	1.72	0.014	0.012
112	0.94	0.99	9.4	1.59	0.017	0.021
113	1.05	1.05	11.6	1.72	0.021	0.019
114	0.94	0.96	9.2	1.62	0.019	0.079
115	0.89	0.93	8.0	1.42	0.014	0.054
Mean	0.998	1.027	9.67	1.565	0.0180	0.0325
SD	0.077	0.078	1.25	0.168	0.0041	0.0223
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
136	1.23	1.13	11.7	1.71	0.026	0.038
137	0.93	0.98	8.9	1.47	0.015	0.032
138	0.93	1.00	8.9	1.41	0.011	0.034
139	0.98	1.02	8.7	1.58	0.014	0.051
140	1.00	1.00	9.4	1.39	0.018	0.015
141	1.14	1.22	10.6	1.66	0.010	0.045
142	0.95	0.98	9.1	1.47	0.023	0.028
143	1.08	1.09	10.8	1.32	0.020	0.055
144	1.11	1.16	12.2	1.11	0.013	0.065
145	1.09	1.21	10.4	1.82	0.023	0.066
Mean	1.044	1.079	10.07	1.494	0.0173	0.0429
SD	0.101	0.095	1.25	0.207	0.0055	0.0165
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
196	1.07	1.09	11.1	1.80	0.005	0.023
197	0.96	1.00	9.6	1.52	0.007	0.012
198	0.88	0.94	9.9	1.27	0.022	0.034
199	0.91	0.97	8.7	1.32	0.023	0.043
200	1.00	1.17	10.2	1.70	0.011	0.056
201	1.12	0.98	10.5	1.51	0.015	0.021
202	1.05	1.00	9.1	1.42	0.022	0.025
203	1.00	1.17	10.2	1.66	0.026	0.095
204	1.07	1.14	9.9	1.43	0.012	0.043
205	1.03	1.11	10.3	1.61	0.024	0.019
Mean	1.009	1.057	9.95	1.524	0.0167	0.0371
SD	0.075	0.088	0.69	0.170	0.0076	0.0244
N	10	10	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 1: Control	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
16	0.015	0.49	0.46	0.011
17	0.015	0.58	0.52	0.013
18	0.012	0.46	0.65	0.009
19	0.014	0.95	0.32	0.015
20	0.018	0.58	0.43	0.011
21	0.013	0.53	0.50	0.011
22	0.016	0.53	0.43	0.019
23	0.015	0.62	0.37	0.014
24	0.019	0.61	0.45	0.014
25	0.013	0.60	0.43	0.012
Mean	0.0150	0.595	0.456	0.0129
SD	0.0022	0.135	0.089	0.0028
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
46	0.015	0.92	0.54	0.012
47	0.009	0.76	0.53	0.007
48	0.014	0.91	0.42	0.012
49	0.011	1.00	0.53	0.012
50	0.014	1.03	0.28	0.017
51	0.013	0.83	0.50	0.007
52	0.011	1.23	0.47	0.016
53	0.013	1.00	0.32	0.010
54	0.018	1.00	0.31	0.018
55	0.011	0.73	0.45	0.010
Mean	0.0129	0.941	0.435	0.0121
SD	0.0026	0.146	0.099	0.0039
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
76	0.015	0.75	0.50	0.011
77	0.015	0.69	0.53	0.008
78	0.014	0.69	0.50	0.013
79	0.015	0.71	0.48	0.013
80	0.014	0.68	0.40	0.014
81	0.012	0.70	0.45	0.009
82	0.019	0.84	0.60	0.010
83	0.012	0.79	0.33	0.011
84	0.017	0.76	0.69	0.008
85	0.016	0.73	0.39	0.016
Mean	0.0149	0.734	0.487	0.0113
SD	0.0021	0.051	0.105	0.0027
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
106	0.016	0.77	0.49	0.010
107	0.015	0.67	0.51	0.009
108	0.010	0.75	0.43	0.010
109	0.014	0.97	0.75	0.012
110	0.020	0.77	0.31	0.009
111	0.014	1.00	0.55	0.009
112	0.015	0.59	0.32	0.009
113	0.014	0.88	0.52	0.007
114	0.010	0.72	0.40	0.009
115	0.012	0.65	0.29	0.010
Mean	0.0140	0.777	0.457	0.0094
SD	0.0029	0.135	0.139	0.0013
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
136	0.017	1.17	0.55	0.007
137	0.017	0.83	0.31	0.017
138	0.012	0.62	0.30	0.008
139	0.015	0.89	0.38	0.012
140	0.013	0.99	0.35	0.005
141	0.014	1.01	0.32	0.007
142	0.015	0.86	0.35	0.010
143	0.014	0.95	0.49	0.007
144	0.010	NT !	0.42	0.009
145	0.016	0.97	0.40	0.012
Mean	0.0143	0.921	0.387	0.0094
SD	0.0022	0.151	0.081	0.0035
N	10	9	10	10

! = Result Comment

FDA-CBER-2021-5683-0767230

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 17 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
196	0.014	1.19	0.38	0.011
197	0.014	0.93	0.33	0.008
198	0.012	0.93	0.36	0.009
199	0.017	0.73	0.32	0.016
200	0.014	0.88	0.35	0.008
201	0.011	0.93	0.64	0.018
202	0.019	0.92	0.44	0.012
203	0.015	0.89	0.44	0.007
204	0.013	1.07	0.41	0.010
205	0.014	1.10	0.23	0.010
Mean	0.0143	0.957	0.390	0.0109
SD	0.0023	0.130	0.108	0.0036
N	10	10	10	10

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
161	0.045	0.043	1.87	0.64	0.68	1.76	1.78
162	0.033	0.030	2.11	0.61	0.65	1.86	1.85
163	0.032	0.035	2.07	0.63	0.67	1.94	1.98
164	0.032	0.040	1.96	0.72	0.73	1.89	2.57
165	0.043	0.034	2.10	0.64	0.69	1.99	1.99
Mean	0.0370	0.0364	2.022	0.648	0.684	1.888	2.034
SD	0.0064	0.0051	0.104	0.042	0.030	0.087	0.312
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
161	1.48	1.64	1.79	14.8	2.33	0.016	0.035
162	1.12	1.50	1.50	11.4	1.63	0.012	0.023
163	1.36	1.48	1.39	13.6	2.50	0.026	0.065
164	1.03	1.42	1.50	12.5	1.83	0.013	0.035
165	1.41	1.68	1.80	13.3	2.93	0.024	0.049
Mean	1.280	1.544	1.596	13.12	2.244	0.0182	0.0414
SD	0.195	0.111	0.187	1.27	0.522	0.0064	0.0161
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
161	0.014	1.162	0.85	0.36	0.018
162	0.012	1.083	0.64	0.31	0.011
163	0.016	0.956	1.04	0.47	0.019
164	0.010	0.958	0.75	0.43	0.008
165	0.012	0.905	0.85	0.47	0.018
Mean	0.0128	1.0128	0.826	0.408	0.0148
SD	0.0023	0.1061	0.148	0.071	0.0050
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
176	0.048	0.048	1.71	0.066	0.058	0.81
177	0.055	0.047	1.92	0.057	0.072	0.87
178	0.042	0.038	1.81	0.043	0.043	0.92
179	0.036	0.044	1.92	0.075	0.058	0.86
180	0.057	0.054	1.89	0.072	0.087	1.05
Mean	0.0476	0.0462	1.850	0.0626	0.0636	0.902
SD	0.0088	0.0058	0.090	0.0129	0.0166	0.091
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
176	0.91	0.95	7.8	1.31	0.011	0.034
177	0.92	0.94	8.1	1.19	0.013	0.055
178	0.96	0.98	8.5	1.25	0.022	0.046
179	0.97	1.04	8.3	1.35	0.013	0.028
180	1.25	1.22	9.9	1.62	0.012	0.039
Mean	1.002	1.026	8.52	1.344	0.0142	0.0404
SD	0.141	0.115	0.81	0.166	0.0044	0.0105
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 31 Relative to Start Date

Group 6: 30 µg/ animal BNT162c1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
176	0.018	0.61	0.50	0.009
177	0.015	0.49	0.36	0.010
178	0.018	0.51	0.41	0.012
179	0.012	0.52	0.39	0.011
180	0.013	0.69	0.48	0.010
Mean	0.0152	0.564	0.428	0.0104
SD	0.0028	0.084	0.060	0.0011
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
11	0.035	0.040	2.16	0.65	0.62	2.16	2.18
12	0.043	0.045	2.09	0.72	0.68	1.94	1.88
13	0.044	0.043	2.02	0.84	0.74	1.96	1.97
14	0.028	0.030	1.99	0.73	0.67	1.90	1.96
15	0.041	0.034	2.12	0.64	0.60	2.58	3.67 >
Mean	0.0382	0.0384	2.076	0.716	0.662	2.108	2.332
SD	0.0067	0.0063	0.070	0.080	0.055	0.282	0.756
N	5	5	5	5	5	5	5

> = Out of range

FDA-CBER-2021-5683-0767238

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
41	0.047	0.052	1.95	0.72	0.75	1.91	1.97
42	0.044	0.044	1.97	0.59	0.61	1.87	1.93
43	0.045	0.039	2.07	0.61	0.61	1.98	2.00
44	0.049	0.050	2.02	0.65	0.62	1.80	NT !
45	0.041	0.034	1.97	0.81	0.73	1.88	1.81
Mean	0.0452	0.0438	1.996	0.676	0.664	1.888	1.928
SD	0.0030	0.0075	0.049	0.090	0.070	0.065	0.083
N	5	5	5	5	5	5	4

! = Result Comment

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
71	0.042	0.041	2.15	0.82	0.81	1.84	1.78
72	0.042	0.034	2.08	0.81	0.74	1.91	1.91
73	0.043	0.046	1.99	0.69	0.72	1.83	1.93
74	0.041	0.039	2.10	0.78	0.80	2.11	2.06
75	0.049	0.052	2.27	0.89	0.97	2.47	2.46
Mean	0.0434	0.0424	2.118	0.798	0.808	2.032	2.028
SD	0.0032	0.0069	0.103	0.073	0.098	0.269	0.261
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
101	0.034	0.034	1.98	0.60	0.58	1.94	1.86
102	0.035	0.027	2.02	0.62	0.64	1.89	1.90
103	0.036	0.031	2.14	0.66	0.55	2.89	3.84 >
104	0.030	0.037	1.78	0.57	0.53	1.78	1.79
105	0.038	0.043	2.06	0.85	0.74	1.90	1.90
Mean	0.0346	0.0344	1.996	0.660	0.608	2.080	2.258
SD	0.0030	0.0061	0.134	0.111	0.085	0.457	0.886
N	5	5	5	5	5	5	5

> = Out of range

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
131	0.038	0.042	2.14	0.79	0.75	2.05	2.00
132	0.037	0.038	2.15	0.79	0.78	1.88	1.90
133	0.039	0.037	2.04	0.83	0.76	1.59	1.62
134	0.038	0.038	2.17	0.93	0.84	2.14	2.14
135	0.045	0.039	1.93	0.70	0.75	2.11	2.17
Mean	0.0394	0.0388	2.086	0.808	0.776	1.954	1.966
SD	0.0032	0.0019	0.101	0.083	0.038	0.227	0.222
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Epididymis (left) (g)	Epididymis (right) (g)	Testis (left) (g)	Testis (right) (g)
191	0.039	0.041	2.01	0.60	0.62	1.87	2.01
192	0.034	0.039	1.87	0.77	0.78	2.09	1.90
193	0.030	0.031	1.95	0.69	0.64	1.95	1.96
194	0.032	0.028	2.09	0.63	0.64	1.86	1.92
195	0.039	0.044	2.07	0.86	0.84	2.06	2.03
Mean	0.0348	0.0366	1.998	0.710	0.704	1.966	1.964
SD	0.0041	0.0068	0.090	0.106	0.099	0.106	0.056
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
11	1.26	1.70	1.85	12.0	2.28	0.022	0.022
12	1.29	1.66	1.73	14.6	1.79	0.026	0.022
13	1.38	1.73	1.83	15.6	2.00	0.022	0.021
14	1.21	1.56	1.77	12.5	2.02	0.015	0.032
15	1.24	1.85	1.83	13.5	2.14	0.012	0.029
Mean	1.276	1.700	1.802	13.64	2.046	0.0194	0.0252
SD	0.065	0.106	0.050	1.48	0.182	0.0057	0.0050
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
41	1.27	1.50	1.60	12.2	2.18	0.018	0.034
42	1.23	1.67	1.74	13.6	2.07	0.043	0.035
43	1.31	1.57	1.62	14.8	2.40	0.011	0.019
44	1.31	1.55	1.46	14.2	2.13	0.018	0.034
45	1.30	1.68	1.65	14.6	1.83	0.010	0.023
Mean	1.284	1.594	1.614	13.88	2.122	0.0200	0.0290
SD	0.034	0.078	0.101	1.04	0.205	0.0134	0.0074
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
71	1.36	1.69	1.65	15.7	2.21	0.016	0.055
72	1.30	1.45	1.60	13.5	1.85	0.016	0.037
73	1.27	1.46	1.54	13.1	1.72	0.020	0.044
74	1.42	1.71	1.72	15.0	2.19	0.030	0.049
75	1.54	2.13	1.80	16.1	2.95	0.030	0.035
Mean	1.378	1.688	1.662	14.68	2.184	0.0224	0.0440
SD	0.107	0.276	0.102	1.33	0.478	0.0071	0.0083
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
101	1.24	1.61	1.61	13.6	2.08	0.013	0.016
102	1.24	1.52	1.59	14.2	2.14	0.013	0.026
103	1.48	1.88	1.88	18.5	2.46	0.026	0.055
104	1.31	1.49	1.43	13.8	2.21	0.012	0.016
105	1.33	1.66	1.76	15.2	2.20	0.020	0.028
Mean	1.320	1.632	1.654	15.06	2.218	0.0168	0.0282
SD	0.098	0.154	0.172	2.02	0.145	0.0061	0.0160
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
131	1.32	1.49	1.50	14.2	1.95	0.017	0.049
132	1.23	1.45	1.56	14.0	1.95	0.017	0.043
133	1.26	1.57	1.67	12.8	1.74	0.020	0.053
134	1.48	1.74	1.87	14.6	2.13	0.013	0.032
135	1.22	1.65	1.72	13.5	2.33	0.022	0.057
Mean	1.302	1.580	1.664	13.82	2.020	0.0178	0.0468
SD	0.107	0.118	0.144	0.69	0.222	0.0034	0.0098
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights						
	Heart (g)	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
191	1.36	1.52	1.62	12.3	2.64	0.020	0.041
192	1.20	1.57	1.64	13.1	2.17	0.019	0.058
193	1.43	1.62	1.70	15.5	2.16	0.015	0.037
194	1.11	1.30	1.32	10.5	1.60	0.015	0.021
195	1.47	1.67	1.73	13.8	2.56	0.019	0.026
Mean	1.314	1.536	1.602	13.04	2.226	0.0176	0.0366
SD	0.154	0.143	0.164	1.85	0.413	0.0024	0.0144
N	5	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
11	0.012	1.505	0.81	0.53	0.022
12	0.013	1.505	0.83	0.46	0.010
13	0.014	1.222	0.89	0.56	0.010
14	0.010	1.119	0.82	0.68	0.009
15	0.014	1.128	0.74	0.38	0.025
Mean	0.0126	1.2958	0.818	0.522	0.0152
SD	0.0017	0.1952	0.054	0.112	0.0077
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
41	0.014	1.110	0.74	0.40	0.011
42	0.015	1.488	0.89	0.62	0.017
43	0.010	1.400	0.97	0.32	0.017
44	0.013	0.915	0.89	0.59	0.010
45	0.009	1.326	0.93	0.44	0.012
Mean	0.0122	1.2478	0.884	0.474	0.0134
SD	0.0026	0.2328	0.087	0.128	0.0034
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
71	0.012	1.281	1.11	0.45	0.013
72	0.012	0.651	0.91	0.40	0.010
73	0.014	0.991	0.72	0.33	0.009
74	0.013	1.304	0.93	0.57	0.015
75	0.015	1.509	1.03	0.59	0.035
Mean	0.0132	1.1472	0.940	0.468	0.0164
SD	0.0013	0.3332	0.147	0.111	0.0107
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
101	0.013	1.259	0.80	0.41	0.016
102	0.014	1.706	0.82	0.50	0.022
103	0.015	0.753	1.01	0.53	0.017
104	0.010	1.009	0.90	0.40	0.007
105	0.015	1.539	0.80	0.54	0.012
Mean	0.0134	1.2532	0.866	0.476	0.0148
SD	0.0021	0.3862	0.090	0.067	0.0056
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
131	0.014	1.268	1.05	0.30	0.017
132	0.015	1.114	0.83	0.35	0.018
133	0.014	1.511	0.86	0.53	0.013
134	0.015	1.520	0.99	0.55	0.011
135	0.014	1.063	0.78	0.49	0.016
Mean	0.0144	1.2952	0.902	0.444	0.0150
SD	0.0005	0.2148	0.113	0.112	0.0029
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Male Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights				
	Pituitary (g)	Prostate Gland (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
191	0.013	1.007	0.84	0.43	0.012
192	0.011	1.462	0.76	0.39	0.011
193	0.014	1.266	0.79	0.56	0.013
194	0.011	0.958	0.85	0.50	0.011
195	0.014	0.636	1.05	0.44	0.012
Mean	0.0126	1.0658	0.858	0.464	0.0118
SD	0.0015	0.3150	0.113	0.067	0.0008
N	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
26	0.066	0.066	1.79	0.053	0.067	1.01
27	0.058	0.061	1.94	0.074	0.097	0.94
28	0.067	0.062	1.96	0.051	0.055	1.05
29	0.054	0.053	1.88	0.065	0.064	1.01
30	0.051	0.051	2.05	0.057	0.065	0.98
Mean	0.0592	0.0586	1.924	0.0600	0.0696	0.998
SD	0.0071	0.0063	0.097	0.0095	0.0160	0.041
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
56	0.048	0.043	1.84	0.077	0.071	0.97
57	0.042	0.032	1.87	0.041	0.044	0.84
58	0.046	0.043	1.90	0.053	0.052	1.09
59	0.055	0.059	2.01	0.057	0.066	0.94
60	0.048	0.047	1.80	0.057	0.096	0.92
Mean	0.0478	0.0448	1.884	0.0570	0.0658	0.952
SD	0.0047	0.0097	0.080	0.0130	0.0200	0.091
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
86	0.044	0.041	1.88	0.044	0.041	0.92
87	0.054	0.050	1.91	0.086	0.083	0.95
88	0.043	0.045	1.92	0.064	0.061	0.99
89	0.037	0.036	1.86	0.063	0.062	1.02
90	0.041	0.042	1.81	0.037	0.059	0.85
Mean	0.0438	0.0428	1.876	0.0588	0.0612	0.946
SD	0.0063	0.0052	0.044	0.0192	0.0149	0.066
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
116	0.053	0.051	1.91	0.059	0.069	0.97
117	0.042	0.044	1.85	0.055	0.068	0.93
118	0.044	0.041	1.94	0.098	0.083	0.92
119	0.053	0.044	1.93	0.053	0.048	1.06
120	0.046	0.038	1.81	0.051	0.045	0.95
Mean	0.0476	0.0436	1.888	0.0632	0.0626	0.966
SD	0.0051	0.0048	0.056	0.0197	0.0159	0.056
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
146	0.045	0.046	1.92	0.067	0.068	0.90
147	0.049	0.050	2.03	0.075	0.074	1.41
148	0.055	0.053	2.02	0.061	0.062	0.99
149	0.052	0.054	2.02	0.062	0.087	1.11
150	0.053	0.048	1.92	0.068	0.064	1.03
Mean	0.0508	0.0502	1.982	0.0666	0.0710	1.088
SD	0.0039	0.0033	0.057	0.0056	0.0100	0.195
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Adren. Gland (left) (g)	Adren. Gland (right) (g)	Brain (g)	Ovary (left) (g)	Ovary (right) (g)	Heart (g)
206	0.056	0.054	1.82	0.050	0.051	0.96
207	0.049	0.050	1.86	0.046	0.059	1.01
208	0.038	0.046	1.88	0.054	0.046	0.85
209	0.060	0.061	1.91	0.043	0.046	0.97
210	0.044	0.043	1.87	0.063	0.068	1.06
Mean	0.0494	0.0508	1.868	0.0512	0.0540	0.970
SD	0.0089	0.0070	0.033	0.0078	0.0095	0.078
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
26	1.04	1.12	10.2	1.53	0.015	0.026
27	1.16	1.28	10.6	1.68	0.027	0.027
28	1.16	1.23	10.6	1.77	0.015	0.018
29	0.93	0.95	9.1	1.45	0.020	0.048
30	1.04	1.06	9.7	1.45	0.018	0.053
Mean	1.066	1.128	10.04	1.576	0.0190	0.0344
SD	0.097	0.132	0.64	0.143	0.0049	0.0152
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
56	0.97	0.97	8.8	1.72	0.028	0.042
57	1.12	1.12	9.6	1.27	0.016	0.045
58	1.09	1.07	11.5	1.87	0.018	0.039
59	1.01	1.04	9.5	1.54	0.010	0.023
60	1.01	1.13	9.5	1.51	0.018	0.039
Mean	1.040	1.066	9.78	1.582	0.0180	0.0376
SD	0.062	0.065	1.01	0.227	0.0065	0.0085
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
86	0.89	0.92	7.6	1.26	0.013	0.030
87	1.15	1.19	9.2	1.45	0.017	0.053
88	1.11	1.17	9.9	1.40	0.023	0.045
89	1.06	1.16	8.6	1.57	0.022	0.026
90	0.83	0.86	7.7	1.29	0.011	0.015
Mean	1.008	1.060	8.60	1.394	0.0172	0.0338
SD	0.140	0.157	0.98	0.125	0.0053	0.0152
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
116	0.99	1.03	8.9	1.35	0.016	0.038
117	1.00	1.08	8.4	1.21	0.010	0.030
118	1.06	1.13	10.0	1.31	0.024	0.052
119	1.12	1.14	9.1	1.62	0.025	0.052
120	1.08	1.05	9.3	1.20	0.018	0.061
Mean	1.050	1.086	9.14	1.338	0.0186	0.0466
SD	0.055	0.048	0.59	0.170	0.0061	0.0124
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
146	0.89	0.94	8.5	1.38	0.056	0.032
147	1.25	1.34	10.4	1.56	0.018	0.038
148	0.97	1.05	9.4	1.41	0.017	0.034
149	1.12	1.18	11.3	1.78	0.022	0.055
150	1.22	1.27	10.4	1.77	0.019	0.031
Mean	1.090	1.156	10.00	1.580	0.0264	0.0380
SD	0.156	0.162	1.07	0.191	0.0167	0.0099
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights					
	Kidney (left) (g)	Kidney (right) (g)	Liver (g)	Lungs (g)	Lymph node (cerv.) (g)	Lymph node (mesent.) (g)
206	0.97	1.04	8.6	1.37	0.020	0.051
207	1.07	1.10	9.4	1.41	0.011	0.052
208	0.85	1.02	8.3	1.32	0.010	0.014
209	1.23	1.26	9.9	1.38	0.023	0.025
210	1.10	1.12	10.4	1.54	0.011	0.027
Mean	1.044	1.108	9.32	1.404	0.0150	0.0338
SD	0.143	0.094	0.88	0.083	0.0060	0.0169
N	5	5	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 1: Control	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
26	0.016	0.77	0.62	0.015
27	0.017	0.62	0.58	0.013
28	0.019	0.86	0.52	0.014
29	0.020	0.62	0.46	0.018
30	0.015	0.69	0.37	0.018
Mean	0.0174	0.712	0.510	0.0156
SD	0.0021	0.103	0.099	0.0023
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 2: 30 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
56	0.018	0.67	0.38	0.019
57	0.015	0.55	0.40	0.012
58	0.016	0.78	0.51	0.014
59	0.017	0.56	0.49	0.019
60	0.018	0.66	0.33	0.010
Mean	0.0168	0.644	0.422	0.0148
SD	0.0013	0.094	0.076	0.0041
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 3: 10 µg/ animal BNT162a1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
86	0.011	0.59	0.33	0.011
87	0.017	0.59	0.66	0.016
88	0.017	0.63	0.44	0.010
89	0.014	0.63	0.41	0.008
90	0.012	0.58	0.41	0.014
Mean	0.0142	0.604	0.450	0.0118
SD	0.0028	0.024	0.124	0.0032
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 4: 30 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
116	0.014	0.55	0.38	0.012
117	0.010	0.55	0.38	0.009
118	0.017	0.70	0.52	0.015
119	0.016	0.57	0.41	0.014
120	0.017	0.58	0.32	0.014
Mean	0.0148	0.590	0.402	0.0128
SD	0.0029	0.063	0.074	0.0024
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 5: 100 µg/ animal BNT162b1	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
146	0.012	0.67	0.40	0.011
147	0.018	0.79	0.42	0.010
148	0.018	0.65	0.46	0.013
149	0.014	0.87	0.63	0.013
150	0.016	0.69	0.52	0.009
Mean	0.0156	0.734	0.486	0.0112
SD	0.0026	0.093	0.093	0.0018
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Sex: Female Day: 38 Relative to Start Date

Group 7: 100 µg/ animal BNT162b2	Absolute Organ Weights			
	Pituitary (g)	Spleen (g)	Thymus (g)	Thyroid/Par. (left) (g)
206	0.013	0.66	0.44	0.012
207	0.020	0.68	0.39	0.015
208	0.017	0.56	0.26	0.008
209	0.015	0.73	0.47	0.008
210	0.016	0.74	0.45	0.010
Mean	0.0162	0.674	0.402	0.0106
SD	0.0026	0.072	0.085	0.0030
N	5	5	5	5

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	5	Male	129	Prostate Gland	Replacement	NT
			Comment:	Not taken at necropsy			

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	17	5	Female	144	Spleen Weight	Replacement	NT
			Comment:	Not taken at necropsy			

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TABLE 15-2 Absolute Organ Weights - Individual Data Rat

Comments and Markers

Page	Day	Group	Sex	Subject	Measurement	Type	Marker
	38	1	Male	15	Testis - Right	Out of Range	>
	38	2	Male	44	Testis - Right	Replacement	NT
			Comment:	Not taken at necropsy			
	38	4	Male	103	Testis - Right	Out of Range	>

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6. HISTOPATHOLOGY REPORT

HISTOPATHOLOGY REPORT

REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS

(b) (4) Project No.38166

27 June 2020

Veterinary Pathologist:
(b) (6), (b) (4)

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HISTOPATHOLOGY REPORT PAGE: I

(b) (4) Study No. 38166

Repeat-Dose Toxicity Study of
Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins by Repeated
Intramuscular Administration
to Wistar Han Rats

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HISTOPATHOLOGY REPORT

(b) (4) Study No. 38166

Repeat-Dose Toxicity Study of
Three LNP-Formulated RNA Platforms
Encoding for Viral Proteins by Repeated
Intramuscular Administration
to Wistar Han Rats

AUTHENTICATION

The undersigned hereby declares that the histopathology data in this report were compiled by him, and that they reflect accurately the primary data records.

(b) (6), (b) (4)

27 June 2020

Date

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PRINCIPAL SECTION

METHODS

Group design for the histopathological evaluation

Text table 1: Group size and dose levels for the histopathological evaluation

Group	Dose level [µg/animal] (Test item / Control)	Number and sex of animals MS + RP	Animal no.	
			MS	RP
1	0 (Buffer) Control	10 + 5 m 10 + 5 f	1 - 10 16 - 25	11 - 15 26 - 30
2	30 (LNP uRNA RBD) BNT162a1	10 + 5 m 10 + 5 f	31 - 40 46 - 55	41 - 45 56 - 60
3	10 (LNP uRNA RBD) BNT162a1	10 + 5 m 10 + 5 f	61 - 70 76 - 85	71 - 75 86 - 90
4	30 (LNP modRNA RBD) BNT162b1	10 + 5 m 10 + 5 f	91 - 100 106 - 115	101 - 105 116 - 120
5	100 (LNP modRNA RBD) BNT162b1	10 + 5 m 10 + 5 f	121 - 130 136 - 145	131 - 135 146 - 150
6	30 (LNP saRNA RBD) BNT162c1	10 + 5 m 10 + 5 f	151 - 160 166 - 175	161 - 165 176 - 180
7	100 (LNP modRNA Sp2) BNT162b2	10 + 5 m 10 + 5 f	181 - 190 196 - 205	191 - 195 206 - 210

MS: Main study
RP: Recovery period
m: male
f: female

The organs listed in section 3.8.10.2 of the main report of all animals of groups 1 to 7 were examined histologically after preparation of paraffin sections and haematoxylin-eosin staining.

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The stained sections from all animals examined were prepared and provided by (b) (4), (b) (4) The macroscopic findings were recorded and provided by (b) (4).

Data compilation

The animal data and macroscopic observations were derived from descriptions recorded by (b) (4), during the post mortem examination of each animal. The histopathological findings of the undersigned pathologist were recorded and calendared using the departmental computerized systems (Provantis® Integrated preclinical software, version 10.2.1, Instem LSS Ltd., United Kingdom).

The histopathological findings recorded in the organs/tissues are summarised in the tables 'Microscopic Findings by Incident' and 'Microscopic Findings by Severity'.

The 'Microscopic Findings by Incident' table lists the frequency of observations per group and sex as percentage of the affected animals per group.

The 'Microscopic Findings by Severity' table lists the severity of observations per group and sex (for severity grading see section 'Explanation of Codes and Symbols').

The 'Tabulated Animal Data' table lists the severity of observations for individual animals.

The 'Individual Animal Data' table comprises the animal data, the macroscopic observations and all microscopic observations of each animal.

The slides were evaluated in April, May and June 2020.

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RESULTS AND CONCLUSION

Mortality

Main study / Recovery period

None of the male and female animals of groups 1 to 7 died or had to be sacrificed prematurely.

Macroscopic findings

BNT162a1 - Groups 2 and 3, BNT162b1 - Groups 4 and 5, BNT162c1 - Group 6, and BNT162b2 - Group 7

Terminal sacrifice

Test item-related macroscopic findings at the end of dosing included injection site findings and increased spleen and draining lymph node (iliac) size. Increased spleen size correlated with increased absolute spleen weights and spleen:body weight ratios.

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Text table 1: Incidences of test item-related macroscopic findings for the animals treated with BNT162a1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened / indurated / (skin) incrusted	3/10	1/10	5/10	5/10
Injection site I (left):				
- Muscle(s) indurated / muscles thickened / indurated	7/10	8/10	10/10	10/10
Spleen:				
- Enlarged	5/10	2/10	2/10	4/10
Lymph node (iliac):				
- Enlarged	4/10	3/10	1/10	1/10

.../... number of animals affected per number of animals examined

Text table 2: Incidences of test item-related macroscopic findings for the animals treated with BNT162b1

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 17				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened	0/10	0/10	1/10	1/10
Injection site I and/or II (left/right):				
- Muscle(s) indurated / muscles thickened / indurated / enlarged	7/10	6/10	7/10	6/10
Spleen:				
- Enlarged	1/10	1/10	5/10	7/10
Lymph node (iliac or renal, left):				
- Enlarged	6/10	4/10	7/10	8/10

.../... number of animals affected per number of animals examined

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Text table 3: Incidences of test item-related macroscopic findings for the animals treated with BNT162c1 or BNT162b2

Incidences of test item-related macroscopic findings in male and female main study animals at necropsy at terminal sacrifice on test day 10 (group 6) or test day 17 (group 7)				
Organ / Finding	**BNT162c1**		**BNT162b2**	
	Group 6: 30 µg/animal		**Group 7: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
External observation:				
- Injection site I and/or II thickened and/or incrusted	9/10	9/10	1/10	1/10
Injection site I and/or II (left/right):				
- Muscle(s) indurated or jellied / thickened / indurated / enlarged	10/10	10/10	7/10	9/10
Spleen:				
- Enlarged	5/10	1/10	2/10	7/10
Lymph node (iliac or iliac/renal):				
- Enlarged	1/10	2/10	5/10	6/10
Sciatic nerve (left):				
- adhered to injection site I	0/10	0/10	0/10	3/10

.../... number of animals affected per number of animals examined

Recovery sacrifice

All macroscopic findings noted at the injection sites and for the spleen had subsided in all animals of all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups)

Enlarged iliac lymph nodes were still noted for a few animals as follows:

Group 4 (30 µg BNT162b1/animal): One of 5 females
Group 5 (100 µg BNT162b1/animal): All 5 males, 2 of 5 females
Group 7 (100 µg BNT162b2/animal): One of 5 males, 3 of 5 females

These findings are regarded to be related to the previous test item treatment.

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Further findings in form of emphysematous lungs, a reddened thymus, an enlarged right testis, a dilated uterus, in some cases filled with clear liquid, a prostate and seminal vesicles that were reduced in size, and enlarged adrenals were noted for individual male and female animals in the test item-treated groups and the control group at terminal sacrifice or at recovery sacrifice. Due to the isolated occurrence per finding, all of these findings are considered as spontaneous changes that are not test item-related.

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Microscopic findings

Terminal sacrifice

Test item-related microscopic findings at the end of dosing included inflammation at the injection site and surrounding tissues, increased cellularity of germinal centers and increased plasma cells in the draining (iliac) lymph node, increased cellularity (hematopoiesis) in the bone marrow and spleen, and vacuolation of hepatocytes in the portal regions. All microscopic findings were partially or fully recovered at the end of the 3 week recovery phase.

Test item-related injection site reactions were present in all groups and characterized by mostly moderate inflammation (up to marked) in males and moderate inflammation in females. The most severe findings were noted consistently in animals administered **100 µg BNT162b1/animal** and **100 µg BNT162b2/animal**, followed by animals administered **30 µg BNT162a1/animal**. The inflammation was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis, at the injection site. Injection site inflammation was associated with mostly moderate edema, mostly mild myofiber degeneration, occasional muscle necrosis, and mostly mild fibrosis. Skin ulceration (mild and moderate) was identified in some males and females administered either **10** or **30 µg BNT162a1/animal** and one animal administered **30 µg BNT162c1/animal**. Injection site findings were partially recovered at the end of the 3-week recovery phase. Inflammation extended into tissues adjacent to the injection site, including mammary tissue, perineural tissue of sciatic nerve, tissue around the femur / knee and to the draining lymph node (iliac). These findings were mostly recovered at the end of the 3-week recovery phase.

Test item-related findings in the draining (iliac) lymph node were characterized by increased cellularity of the follicular germinal centers and increased plasma cells (plasmacytosis) and were variably present in all groups.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen were present in all groups.

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A test item-related vacuolation of hepatocytes in the portal regions of the liver was present in all groups.

A few minor microscopic changes were recorded for the organs examined in this study. The type, incidence and severity of all microscopic findings observed did not indicate any relationship to the treatment with the test item. All changes are regarded to be spontaneous in nature being within the normal background pathology commonly seen in rats of this strain and age.

Test item-related findings were noted for all test items and all dose levels in male and female animals as given in the text tables following on the next pages.

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Text table 4: Incidences of test item-related microscopic findings for the animals treated with BNT162a1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162a1**			
	Group 3: 10 µg/animal		**Group 2: 30 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site l (left):				
- Fibrosis intramuscular/interstitial	10/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	10/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	9/10**	9/10**	9/10**
- Edema, subcutis	10/10**	9/10**	6/10*	10/10**
- Edema intramuscular/interstitial	7/10**	8/10**	2/10	10/10**
- Edema inter-/ perimuscular	10/10**	10/10**	7/10**	10/10**
- Hyperplasia, epidermis	9/10**	7/10**	10/10**	9/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	1/10	3/10	0/10
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	1/10	0/10	1/10
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	3/10	0/10	0/10
Lymph node (iliac):				
- Plasmacytosis	7/10**	7/10**	5/10*	3/10
- Inflammation	0/10	3/10	5/10*	6/10*
- Increased cellularity, germinal center	9/10	10/10**	9/10	8/10
Spleen:				
- Increased haematopoiesis	3/10	2/10	0/10	0/10
Liver				
- Vacuolation, hepatocellular, periportal	1/10	6/10*	1/10	10/10**

.../... number of animals affected per number of animals examined
* significantly different from control ($p \leq 0.05$)
** significantly different from control ($p \leq 0.01$)

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Text table 5: Incidences of test item-related microscopic findings for the animals treated with BNT162b1

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 17				
Organ / Finding	**BNT162b1**			
	Group 4: 30 µg/animal		**Group 5: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed.	10/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	9/10**	10/10**	10/10**	10/10**
- Edema, subcutis	9/10**	10/10**	10/10**	10/10**
- Edema intramuscular/interstitial	8/10**	9/10**	10/10**	10/10**
- Edema inter-/ perimuscular	10/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	8/10**	10/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	1/10	4/10	7/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	4/10	6/10*
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	0/10	2/10	1/10
Lymph node (iliac):				
- Plasmacytosis	9/10**	8/10**	8/10**	10/10**
- Inflammation	0/10	0/10	5/10*	8/9**
- Increased cellularity, geminal center	10/10	8/10	10/10	10/10**
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	7/10**
Liver				
- Vacuolation, hepatocellular, periportal	0/10	10/10**	8/10**	10/10**

.../... number of animals affected per number of animals examined
* significantly different from control ($p \leq 0.05$)
** significantly different from control ($p \leq 0.01$)

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Text table 6: Incidences of test item-related microscopic findings for the animals treated with BNT162c1 and BNT162b2

Incidences of test item-related microscopic findings in male and female main study animals after terminal sacrifice on test day 10 (group 6) or test day 17 (group 7)				
Organ / Finding	**BNT162c1**		**BNT162b2**	
	Group 6: 30 µg/animal		**Group 7: 100 µg/animal**	
	Males	**Females**	**Males**	**Females**
Bone marrow:				
- Increased cellularity	10/10**	10/10**	10/10**	10/10**
Injection site I and/or II (left/right):				
- Fibrosis intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Fibrosis inter-/perimuscular	9/10**	10/10**	10/10**	10/10**
- Inflammation, mixed	9/10**	10/10**	10/10**	10/10**
- Myofiber degeneration	8/10**	9/10**	10/10**	10/10**
- Edema, subcutis	9/10**	10/10**	10/10**	10/10**
- Edema intramuscular/interstitial	9/10**	10/10**	10/10**	10/10**
- Edema inter-/ perimuscular	9/10**	10/10**	10/10**	10/10**
- Hyperplasia, epidermis	9/10**	10/10**	9/10**	10/10**
Surrounding tissue of injection sites:				
Perineural tissue of sciatic nerve:				
- Inflammation (perineural)	0/10	0/10	10/10**	10/10**
Bone, os femoris with joint (surrounding tissue):				
- Inflammation	0/10	0/10	2/10	9/10**
Mammary gland (Interstitial tissue):				
- Inflammation	0/10	4/10	2/10	0/10
Lymph node (iliac):				
- Plasmacytosis	6/10*	7/10**	10/10**	10/10**
- Inflammation	4/10	7/10**	9/10**	6/10*
- Increased cellularity, germinal center	10/10	10/10**	10/10	10/10**
Skeletal muscle:				
- Infiltration, lymphohistiogranulocyt.	0/10	0/10	5/10*	0/10
Spleen:				
- Increased haematopoiesis	0/10	0/10	2/10	8/10**
Liver				
- Vacuolation, hepatocellular, periportal	1/10	10/10**	9/10**	10/10**

.../... number of animals affected per number of animals examined
* significantly different from control ($p \leq 0.05$)
** significantly different from control ($p \leq 0.01$)

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Recovery sacrifice

Most of the microscopic findings noted at the injection sites, iliac lymph node, surrounding tissue of the injection sites (surrounding tissue of bone, os femoris with joint; perineural tissue of sciatic nerve; interstitial tissue of mammary gland; skeletal muscle) and spleen had subsided in all animals of all previously test item-treated groups at the end of the recovery period (test day 31 for group 6, test day 38 for all other groups). Some inflammatory lesions were still noted at the injection sites and the surrounding tissue of some animals.

Test item-related minimal to mild increases in the cellularity of bone marrow and extramedullary hematopoiesis in the spleen were fully recovered at the end of the 3-week recovery phase.

Test item-related vacuolation of hepatocytes in the portal regions of the liver was fully recovered at the end of the 3-week recovery phase.

The incidence and the severity of the remaining findings were markedly reduced compared to the main study animals.

The infiltration of macrophages in the iliac lymph nodes of previously treated recovery animals were regarded as consequence of phagocytosis relating to the inflammatory reactions at the injection sites.

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Discussion synopsis

Injection site inflammation, as well as inflammation in the adjacent tissues, was an anticipated response to an immune response to the administered test article. Inflammation was generally most severe in animals administered **100 µg** of either **BNT162b1** or **BNT162b2/animal** at the end of dosing, followed by **30 µg BNT162a1/animal**. Ulceration at the injection site was present only in rats administered **BNT162a1**. The inflammation was partially or fully resolved at the end of the recovery phase, indicating reversibility.

Increased cellularity of the germinal centers of the draining (iliac) lymph node and plasmacytosis is consistent with the anticipated immune activation by the test articles and inflammation at the injection site.

Increases in bone marrow cellularity (increased hematopoiesis) and extramedullary hematopoiesis in the spleen are consistent with a response to inflammation and immune responses induced by the test article.

Test item-related vacuolation of portal hepatocytes was present in all groups. The vacuolation was unassociated with markers of hepatocyte damage (i.e. ALAT, ASAT) and has been reported in animals administered pegylated compounds. The findings were fully reversed at the end of the recovery phase.

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EXPLANATION OF CODES AND SYMBOLS

Tissue Result

N	tissue within normal histological limits
.	not recorded
+	tissue observation present
X	not examined

Grade

.	not recorded
1	minimal
2	mild
3	moderate
4	marked
#	different severities recorded, e.g. for the two parts of a paired organ
P	present - no grade or classification

Symbols

%	per cent
*	statistically significant (at $p \leq 0.05$, exact test of R. A. FISHER)
**	statistically significant (at $p \leq 0.01$, exact test of R. A. FISHER)
TGL	trackable gross lesion

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TABLES

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
ADRENAL GLAND, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	73.3%	66.7%	73.3%	80.0%	86.7%	73.3%	80.0%	80.0%	60.0%	80.0%	93.3%	86.7%	80.0%
Dilation; vascular	13.3%	26.7%	33.3%	26.7%	20.0%	13.3%	20.0%	20.0%	20.0%	33.3%	20.0%	6.7%	13.3%	20.0%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	80.0%	80.0%	100.0%	80.0%	86.7%	73.3%	86.7%	86.7%	86.7%	86.7%	86.7%	100.0%	93.3%
Dilation; vascular	13.3%	20.0%	20.0%	0.0%	20.0%	13.3%	20.0%	13.3%	13.3%	6.7%	13.3%	13.3%	0.0%	6.7%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
AORTA ABDOMINALIS;														
Examined	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	66.7%	100.0%	86.7%	100.0%	93.3%	93.3%	100.0%	53.3%	100.0%	40.0%
Inflammation; mixed; surrounding tissue	0.0%	0.0%	0.0%	0.0%	26.7%	0.0%	13.3%	0.0%	6.7%	6.7%	0.0%	40.0%	0.0%	60.0%
Infiltration, Lymphocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
BONE MARROW, OS FEMORIS WITH JOINT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%	100.0%	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%
Increased Cellularity	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
BONE, STERNUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	93.3%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; muscle	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
BRAIN, BRAIN STEM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(14)
Within Normal Limits	-	-	-	-	-	-	-	80.0%	53.3%	66.7%	66.7%	73.3%	66.7%	78.6%
Keratinization; epithelial	-	-	-	-	-	-	-	20.0%	46.7%	33.3%	33.3%	26.7%	33.3%	21.4%
Cyst; keratinized	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
EPIDIDYMIS, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	26.7%	13.3%	13.3%	53.3%	33.3%	33.3%	26.7%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	73.3%	86.7%	86.7%	46.7%	66.7%	66.7%	73.3%	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	33.3%	13.3%	20.0%	33.3%	26.7%	26.7%	13.3%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	66.7%	86.7%	80.0%	60.0%	73.3%	73.3%	86.7%	-	-	-	-	-	-	-

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(b)(4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
EPIDIDYMIS, RIGHT; (continued)														
Infiltration; mixed	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Oligospermia	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
ESOPHAGUS;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EYE, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	93.3%	100.0%	100.0%	86.7%	93.3%	100.0%	93.3%	93.3%	80.0%	73.3%	73.3%	86.7%	73.3%	93.3%
Infiltration, Lymphocytic	6.7%	0.0%	0.0%	13.3%	6.7%	0.0%	0.0%	0.0%	13.3%	0.0%	13.3%	6.7%	6.7%	6.7%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	6.7%	6.7%	6.7%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	6.7%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
HARDERIAN GLAND, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	93.3%	93.3%	100.0%	86.7%	80.0%	100.0%	93.3%	93.3%	86.7%	100.0%	100.0%	93.3%	73.3%
Infiltration, Lymphocytic	13.3%	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	6.7%	26.7%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
HARDERIAN GLAND, RIGHT; (continued)														
Inflammation, Chronic	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	80.0%	86.7%	80.0%	93.3%	100.0%	86.7%	100.0%	86.7%	93.3%	93.3%	93.3%	93.3%	100.0%
Infiltration; lymphohistiocytic	0.0%	6.7%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	13.3%	6.7%	6.7%	6.7%	0.0%	13.3%	0.0%	6.7%	6.7%	0.0%	6.7%	6.7%	0.0%
INJECTION SITE I;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	60.0%	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%
Fibrosis; intramuscular / interstitial	0.0%	66.7%	86.7%	86.7%	86.7%	60.0%	93.3%	0.0%	86.7%	73.3%	93.3%	73.3%	66.7%	93.3%
Fibrosis; inter- / perimuscular	0.0%	100.0%	100.0%	93.3%	100.0%	66.7%	100.0%	0.0%	100.0%	100.0%	100.0%	100.0%	93.3%	93.3%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%
Hemorrhage; subcutis	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	13.3%	13.3%	33.3%	26.7%	0.0%	20.0%	0.0%	26.7%	6.7%	26.7%	6.7%	0.0%	26.7%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	33.3%	26.7%	33.3%	33.3%	6.7%	33.3%	0.0%	26.7%	20.0%	33.3%	26.7%	20.0%	26.7%
Inflammation; neutrophilic; dermis; epidermis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Inflammation; plasmacytic; perivascular	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; vascular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Inflammation; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	66.7%	66.7%	66.7%	66.7%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
Inflammation; mixed; intramuscular / interstitial	0.0%	60.0%	66.7%	66.7%	60.0%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
INJECTION SITE I; (continued)														
Inflammation; mixed; inter- / perimuscular	0.0%	66.7%	66.7%	66.7%	66.7%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
Mineralization; inter- / perimuscular	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
Necrosis; dermis; subcutis	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermis	0.0%	13.3%	13.3%	0.0%	0.0%	6.7%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	13.3%	13.3%
Degeneration; myofiber	6.7%	60.0%	60.0%	60.0%	66.7%	53.3%	66.7%	0.0%	60.0%	60.0%	66.7%	66.7%	60.0%	66.7%
Regeneration; muscle	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Material; hair	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	40.0%	66.7%	60.0%	53.3%	60.0%	66.7%	0.0%	66.7%	60.0%	66.7%	66.7%	66.7%	66.7%
Edema; intramuscular / interstitial	0.0%	13.3%	46.7%	53.3%	53.3%	60.0%	66.7%	0.0%	66.7%	53.3%	60.0%	66.7%	66.7%	66.7%
Edema; inter- / perimuscular	0.0%	46.7%	66.7%	66.7%	53.3%	60.0%	66.7%	0.0%	66.7%	66.7%	66.7%	66.7%	66.7%	66.7%
Hyperkeratosis; epidermal	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	60.0%	60.0%	60.0%	66.7%	60.0%	60.0%	0.0%	60.0%	46.7%	53.3%	66.7%	66.7%	66.7%
Scab; epidermal	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	6.7%	6.7%
Pustule; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Multinucleated Macrophages; inter- / perimuscular	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;														
Examined	(15)	(5)	(0)	(0)	(15)	(0)	(15)	(15)	(1)	(0)	(0)	(15)	(0)	(15)
Within Normal Limits	66.7%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%
Degeneration; myofiber	0.0%	60.0%	0.0%	0.0%	66.7%	0.0%	66.7%	6.7%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Regeneration; muscle	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	46.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	60.0%
Scab; epidermal	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	60.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Edema; inter- / perimuscular	0.0%	40.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Edema; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Necrosis; myofiber	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Necrosis; dermis; subcutis	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; traumatic; myofiber	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; inter- / perimuscular	0.0%	60.0%	0.0%	0.0%	100.0%	0.0%	100.0%	0.0%	100.0%	0.0%	0.0%	93.3%	0.0%	93.3%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
INJECTION SITE II; (continued)														
Fibrosis; intramuscular / interstitial ..	0.0%	60.0%	0.0%	0.0%	93.3%	0.0%	86.7%	0.0%	0.0%	0.0%	0.0%	80.0%	0.0%	80.0%
Fibrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermal	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	26.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	26.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%	33.3%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	26.7%
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	33.3%	0.0%	26.7%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	20.0%
Inflammation; mixed	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Inflammation; mixed; inter- / perimuscular	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
Inflammation; mixed; intramuscular / interstitial	0.0%	80.0%	0.0%	0.0%	66.7%	0.0%	66.7%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	66.7%
INTESTINE, CECUM;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	93.3%	93.3%	100.0%	86.7%	80.0%	100.0%	100.0%	100.0%	93.3%	86.7%	80.0%	86.7%	100.0%	93.3%
Hyperplasia; mucosa-associated lymphoid tissue	6.7%	6.7%	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	6.7%	13.3%	6.7%	0.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased ...	0.0%	0.0%	0.0%	6.7%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	13.3%	0.0%	6.7%
INTESTINE, COLON;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	93.3%	93.3%	60.0%	86.7%	66.7%	80.0%	100.0%	100.0%	100.0%	80.0%	86.7%	86.7%	73.3%	86.7%
Hyperplasia; mucosa-associated lymphoid tissue	6.7%	6.7%	40.0%	13.3%	20.0%	20.0%	0.0%	0.0%	0.0%	20.0%	13.3%	6.7%	26.7%	0.0%
Infiltration, Eosinophilic; increased ...	0.0%	0.0%	0.0%	6.7%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	6.7%	0.0%	13.3%
INTESTINE, DUODENUM;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
INTESTINE, ILEUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	86.7%	80.0%	73.3%	86.7%	60.0%	93.3%	86.7%	80.0%	80.0%	93.3%	60.0%	86.7%	93.3%	46.7%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	13.3%	26.7%	0.0%	0.0%	6.7%	0.0%	0.0%	33.3%	13.3%	0.0%	40.0%
Hyperplasia; mucosa-associated lymphoid tissue	13.3%	20.0%	26.7%	0.0%	20.0%	6.7%	13.3%	6.7%	20.0%	6.7%	6.7%	6.7%	6.7%	13.3%
Nematodiasis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Congestion	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%
Basophilia; tubule	13.3%	6.7%	6.7%	13.3%	6.7%	20.0%	13.3%	13.3%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%
Infiltration, Lymphocytic	26.7%	6.7%	26.7%	20.0%	6.7%	0.0%	20.0%	6.7%	13.3%	6.7%	6.7%	13.3%	6.7%	0.0%
Mineralization	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	6.7%
Cyst; tubular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	13.3%	6.7%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%
Degeneration; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	6.7%	6.7%	6.7%	13.3%	26.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	6.7%	6.7%	20.0%	6.7%	6.7%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%
Inflammation; purulent; pelvis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
KIDNEY, RIGHT; (continued)														
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	6.7%	13.3%	6.7%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	13.3%
Dilation; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; subcapsular	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pyelonephritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	93.3%	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hematopoiesis; extramedullary	13.3%	26.7%	13.3%	20.0%	6.7%	6.7%	13.3%	20.0%	20.0%	6.7%	46.7%	33.3%	40.0%	33.3%
Infiltration; mixed	6.7%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	6.7%
Necrosis	6.7%	0.0%	0.0%	13.3%	0.0%	13.3%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	60.0%	33.3%	66.7%	53.3%	40.0%	13.3%	33.3%	60.0%	26.7%	46.7%	40.0%	13.3%	33.3%	13.3%
Vacuolation; hepatocellular	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; hepatocellular; periportal	6.7%	6.7%	6.7%	0.0%	53.3%	6.7%	60.0%	0.0%	66.7%	40.0%	66.7%	66.7%	73.3%	66.7%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; kupffer cell	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LUNGS WITH BRONCHI;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	20.0%	26.7%	40.0%	20.0%	33.3%	33.3%	46.7%	73.3%	53.3%	60.0%	33.3%	40.0%	66.7%	26.7%
Ossification	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
LUNGS WITH BRONCHI; (continued)														
Hemorrhage; acute	26.7%	20.0%	33.3%	33.3%	20.0%	26.7%	33.3%	6.7%	13.3%	13.3%	6.7%	6.7%	6.7%	0.0%
Hyperplasia; bronchial-associated lymphoid tissue	46.7%	60.0%	33.3%	60.0%	40.0%	40.0%	20.0%	13.3%	26.7%	26.7%	46.7%	26.7%	33.3%	33.3%
Infiltration, Eosinophilic; perivascular	20.0%	6.7%	6.7%	13.3%	20.0%	6.7%	6.7%	6.7%	0.0%	13.3%	26.7%	13.3%	0.0%	53.3%
Infiltration; macrophage; alveolus	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%
Pigmentation; brown; macrophage	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
LYMPH NODE, CERVICAL;														
Examined	(13)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	93.3%	86.7%	100.0%	93.3%	86.7%	93.3%	86.7%	100.0%	93.3%	100.0%	86.7%	92.9%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	6.7%	0.0%
Hemorrhage	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	86.7%	100.0%	100.0%	93.3%	100.0%	100.0%	85.7%
LYMPH NODE, ILIAC;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(14)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	93.3%	100.0%	93.3%	100.0%	93.3%	93.3%	93.3%	93.3%	73.3%	66.7%	100.0%	100.0%	92.9%
Plasmacytosis	0.0%	33.3%	46.7%	73.3%	73.3%	40.0%	73.3%	0.0%	40.0%	66.7%	73.3%	100.0%	53.3%	100.0%
Infiltration, Eosinophilic	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation	0.0%	33.3%	0.0%	0.0%	33.3%	26.7%	60.0%	0.0%	40.0%	20.0%	0.0%	50.0%	46.7%	42.9%
Infiltration; macrophage	0.0%	0.0%	6.7%	6.7%	33.3%	20.0%	33.3%	0.0%	20.0%	0.0%	20.0%	35.7%	33.3%	28.6%
Increased Cellularity; germinal center	86.7%	93.3%	93.3%	100.0%	100.0%	100.0%	100.0%	46.7%	86.7%	100.0%	86.7%	100.0%	93.3%	100.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
LYMPH NODE, MESENTERIC;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	92.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
Pigmentation; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
Increased Cellularity; germinal center	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	93.3%	86.7%
LYMPH NODE, RENAL;														
Examined	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
MAMMARY GLANDS;														
Examined	(14)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	86.7%	73.3%	100.0%	100.0%	100.0%	80.0%	100.0%	93.3%	80.0%	100.0%
Inflammation; mixed; interstitium	0.0%	0.0%	0.0%	0.0%	13.3%	20.0%	0.0%	0.0%	0.0%	20.0%	0.0%	6.7%	20.0%	0.0%
Inflammation; mixed; interstitium; lymphatic	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SKELETAL MUSCLE;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	66.7%	93.3%	93.3%	93.3%	100.0%	80.0%	100.0%	93.3%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	33.3%	0.0%	6.7%	0.0%	0.0%	13.3%	0.0%	0.0%
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
NERVE, SCIATIC;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	100.0%	80.0%	100.0%	93.3%	53.3%	100.0%	20.0%	100.0%	100.0%	86.7%	73.3%	26.7%	100.0%	26.7%
Inflammation; perineural	0.0%	20.0%	0.0%	6.7%	46.7%	0.0%	80.0%	0.0%	0.0%	6.7%	26.7%	73.3%	0.0%	73.3%
Vacuolation	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, LEFT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(14)	(15)	(15)	(15)
Within Normal Limits	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	86.7%	86.7%	100.0%	100.0%	93.3%	93.3%
Not Examined: INSUFFICIENT TISSUE TO EVALUATE	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	6.7%	6.7%
Pigmentation; brown; macrophage	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, RIGHT;														
Examined	(15)	(12)	(15)	(14)	(15)	(15)	(14)	(15)	(14)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	91.7%	93.3%	92.9%	100.0%	100.0%	100.0%	100.0%	92.9%	93.3%	93.3%	100.0%	93.3%	100.0%
Pigmentation; brown; macrophage	0.0%	8.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	6.7%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
OVARY, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVARY, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(14)	(15)	(15)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
OVIDUCT, LEFT; (continued)														
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(14)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PANCREAS;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	93.3%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	93.3%	86.7%	100.0%	100.0%	100.0%
Not Examined: NOT PRESENT	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Atrophy; acinar cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Hyperplasia; acinar cell	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	0.0%
PARATHYROID, LEFT;														
Examined	(8)	(12)	(11)	(7)	(14)	(12)	(11)	(14)	(15)	(7)	(13)	(10)	(14)	(9)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	90.0%	100.0%	88.9%
Fibrosis; interstitial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	10.0%	0.0%	11.1%
PARATHYROID, RIGHT;														
Examined	(13)	(10)	(11)	(8)	(11)	(12)	(12)	(12)	(15)	(10)	(13)	(8)	(12)	(11)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;														
Examined	(12)	(9)	(13)	(14)	(15)	(14)	(12)	(15)	(11)	(13)	(13)	(12)	(11)	(14)
Within Normal Limits	8.3%	11.1%	0.0%	0.0%	6.7%	7.1%	0.0%	0.0%	0.0%	7.7%	15.4%	0.0%	0.0%	7.1%
Not Examined: NOT PRESENT	25.0%	66.7%	15.4%	7.1%	0.0%	7.1%	25.0%	0.0%	36.4%	15.4%	15.4%	25.0%	36.4%	7.1%
Mineralization	8.3%	11.1%	15.4%	7.1%	0.0%	14.3%	8.3%	0.0%	0.0%	7.7%	0.0%	8.3%	9.1%	7.1%
Inflammation, Granulomatous; follicular	8.3%	0.0%	7.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.7%	7.7%	8.3%	0.0%	0.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
PEYERS PATCHES; (continued)														
Increased Cellularity; germinal center ..	91.7%	88.9%	100.0%	100.0%	93.3%	92.9%	100.0%	100.0%	100.0%	92.3%	84.6%	100.0%	100.0%	92.9%
PITUITARY GLAND;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)
Within Normal Limits	93.3%	86.7%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	93.3%	93.3%	100.0%	100.0%	93.3%	100.0%
Cyst; pars distalis	0.0%	13.3%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%
Cyst; pars intermedia	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
PROSTATE GLAND;														
Examined	(15)	(14)	(15)	(15)	(14)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	80.0%	85.7%	66.7%	60.0%	85.7%	73.3%	86.7%	-	-	-	-	-	-	-
Infiltration; mixed	0.0%	7.1%	6.7%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Inflammation; purulent	6.7%	0.0%	0.0%	6.7%	7.1%	13.3%	0.0%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	13.3%	7.1%	26.7%	26.7%	7.1%	13.3%	13.3%	-	-	-	-	-	-	-
SALIVARY GLANDS, MANDIBULAR;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(14)	(15)	(15)	(14)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;														
Examined	(15)	(15)	(14)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SEMINAL VESICLES;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
SEMINAL VESICLES; (continued)														
Within Normal Limits	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	-	-	-	-	-	-	-
Infiltration; mixed; surrounding tissue; fat	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	-	-	-	-	-	-	-
Infiltration, Lymphocytic	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
SKIN;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	60.0%
Infiltration; mixed; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	40.0%
Infiltration; mixed; subcutaneous	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SPINAL CORD;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%
SPLEEN;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	20.0%	6.7%	53.3%	26.7%	33.3%	53.3%	53.3%	20.0%	20.0%	46.7%	20.0%	40.0%	20.0%	13.3%
Congestion	80.0%	93.3%	40.0%	73.3%	53.3%	46.7%	40.0%	80.0%	80.0%	46.7%	80.0%	40.0%	80.0%	66.7%
Hematopoiesis; increased	0.0%	0.0%	20.0%	0.0%	13.3%	0.0%	13.3%	0.0%	0.0%	13.3%	0.0%	46.7%	0.0%	53.3%
STOMACH, GLANDULAR;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	6.7%	0.0%	33.3%	13.3%	6.7%	33.3%	0.0%	6.7%	20.0%	40.0%	0.0%	0.0%	46.7%	20.0%
Infiltration, Eosinophilic	93.3%	93.3%	60.0%	86.7%	93.3%	60.0%	93.3%	93.3%	66.7%	53.3%	100.0%	100.0%	46.7%	73.3%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Dilation; glandular	0.0%	13.3%	13.3%	6.7%	6.7%	6.7%	6.7%	0.0%	6.7%	13.3%	6.7%	6.7%	6.7%	13.3%
Cyst	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; chief cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	6.7%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	13.3%	0.0%	6.7%	6.7%	0.0%	6.7%	0.0%	0.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
STOMACH, GLANDULAR; (continued)														
Infiltration, Neutrophilic; mucosa	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
STOMACH, NONGLANDULAR;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits.....	86.7%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	-	-	-	-	-	-	-
Spermatid Giant Cells	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Dilation; tubular	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
TESTIS, RIGHT;														
Examined.....	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits.....	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	-	-	-	-	-	-	-
Not Examined: NOT PRESENT	0.0%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Dilation; tubular	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Infiltration; lymphoplasmacytic	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
Spermatocoele	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-	-	-	-	-	-	-
THYMUS;														
Examined.....	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits.....	66.7%	46.7%	46.7%	60.0%	60.0%	46.7%	53.3%	46.7%	33.3%	80.0%	60.0%	66.7%	53.3%	40.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Hemorrhage; acute	33.3%	53.3%	53.3%	40.0%	40.0%	53.3%	46.7%	53.3%	66.7%	20.0%	40.0%	33.3%	40.0%	60.0%
THYROID, LEFT;														
Examined.....	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)	(15)	(15)
Within Normal Limits.....	86.7%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	93.3%	80.0%	92.9%	100.0%	93.3%	100.0%	100.0%
Cyst; keratinized	13.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	20.0%	7.1%	0.0%	6.7%	0.0%	0.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
THYROID, RIGHT;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)
Within Normal Limits	93.3%	86.7%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	100.0%	100.0%	85.7%	100.0%
Cyst; keratinized	6.7%	13.3%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	14.3%	0.0%
TONGUE;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	93.3%	100.0%	93.3%	100.0%	100.0%	100.0%	100.0%	93.3%	100.0%	100.0%	93.3%	100.0%	93.3%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Granuloma	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%
Granuloma; hair	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;														
Examined	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	66.7%	93.3%	80.0%	80.0%	86.7%	100.0%	100.0%	86.7%	86.7%	86.7%	80.0%	93.3%	93.3%	93.3%
Infiltration; lymphohistiocytic	20.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	6.7%	0.0%	13.3%	13.3%	13.3%	0.0%	0.0%	13.3%	0.0%	6.7%	20.0%	6.7%	0.0%	0.0%
Pigmentation; brown; macrophage	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	6.7%	6.7%	0.0%	6.7%	0.0%	0.0%	0.0%	0.0%	6.7%	6.7%	0.0%	0.0%	6.7%	6.7%
URINARY BLADDER;														
Examined	(15)	(14)	(15)	(14)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(14)	(15)	(15)
Within Normal Limits	100.0%	100.0%	93.3%	92.9%	100.0%	100.0%	100.0%	86.7%	100.0%	100.0%	100.0%	92.9%	100.0%	93.3%
Infiltration, Lymphocytic	0.0%	0.0%	6.7%	7.1%	0.0%	0.0%	0.0%	13.3%	0.0%	0.0%	0.0%	7.1%	0.0%	6.7%
UTERUS;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	100.0%	80.0%	66.7%	86.7%	93.3%	100.0%	93.3%
Dilation	-	-	-	-	-	-	-	0.0%	20.0%	33.3%	13.3%	6.7%	0.0%	6.7%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: All of those SELECTED	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	15	15	15	15	15	15	15	15	15	15	15	15	15	15
Number of Animals Completed:	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
VAGINA;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(15)	(15)	(15)	(15)	(15)	(15)	(15)
Within Normal Limits	-	-	-	-	-	-	-	73.3%	46.7%	53.3%	66.7%	60.0%	60.0%	60.0%
Keratinization; epithelial	-	-	-	-	-	-	-	26.7%	53.3%	46.7%	33.3%	40.0%	40.0%	40.0%

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
ADRENAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	60.0%	90.0%	90.0%	90.0%	80.0%
Dilation; vascular	10.0%	10.0%	40.0%	10.0%	10.0%	10.0%	10.0%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
ADRENAL GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	70.0%	100.0%	80.0%	100.0%	80.0%
Dilation; vascular	10.0%	10.0%	30.0%	0.0%	20.0%	0.0%	10.0%
Hypertrophy; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
AORTA ABDOMINALIS;							
Examined	(10)	(9)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	60.0%	100.0%	80.0%
Inflammation; mixed; surrounding tissue	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	20.0%
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
BONE, STERNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; muscle	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
BRAIN, BRAIN STEM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-
EPIDIDYMIS, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	30.0%	20.0%	10.0%	70.0%	30.0%	40.0%	10.0%
Infiltration, Lymphocytic	70.0%	80.0%	90.0%	30.0%	70.0%	60.0%	90.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
EPIDIDYMIS, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	30.0%	10.0%	30.0%	40.0%	20.0%	40.0%	0.0%
Infiltration, Lymphocytic	70.0%	90.0%	70.0%	50.0%	80.0%	60.0%	100.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
ESOPHAGUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EYE, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	90.0%	90.0%	100.0%	90.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	10.0%	10.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	80.0%	100.0%	90.0%	100.0%	80.0%	70.0%	100.0%
Infiltration, Lymphocytic	20.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	90.0%	80.0%	90.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%
INJECTION SITE I;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	40.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Fibrosis; intramuscular / interstitial	0.0%	90.0% **	100.0% **	90.0% **	90.0% **	90.0% **	100.0% **
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	90.0% **	100.0% **	90.0% **	100.0% **
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Hemorrhage; subcutis	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	60.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; neutrophilic; dermis; epidermis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; plasmacytic; perivascular	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Inflammation; vascular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)							
Inflammation; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	90.0% **	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	90.0% **	100.0% **	100.0% **	90.0% **	90.0% **	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	90.0% **	100.0% **
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Necrosis; dermis; subcutis	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermis	0.0%	20.0%	20.0%	0.0%	0.0%	10.0%	0.0%
Degeneration; myofiber	10.0%	90.0% **	90.0% **	90.0% **	100.0% **	80.0% **	100.0% **
Regeneration; muscle	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Material; hair	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	60.0% *	100.0% **	90.0% **	80.0% **	90.0% **	100.0% **
Edema; intramuscular / interstitial	0.0%	20.0%	70.0% **	80.0% **	80.0% **	90.0% **	100.0% **
Edema; inter- / perimuscular	0.0%	70.0% **	100.0% **	100.0% **	80.0% **	90.0% **	100.0% **
Hyperkeratosis; epidermal	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	90.0% **	90.0% **	90.0% **	100.0% **	90.0% **	90.0% **
Scab; epidermal	0.0%	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%
Pustule; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;							
Examined	(10)	(4)	(0)	(0)	(10)	(0)	(10)
Within Normal Limits	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Degeneration; myofiber	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	100.0% **
Regeneration; muscle	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	70.0% **
Scab; epidermal	0.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; inter- / perimuscular	0.0%	50.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Necrosis; myofiber	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)							
Necrosis; dermis; subcutis	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; traumatic; myofiber	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Fibrosis; inter- / perimuscular	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	100.0% **
Fibrosis; intramuscular / interstitial	0.0%	75.0% *	0.0%	0.0%	100.0% **	0.0%	90.0% **
Ulceration; epidermal	0.0%	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Inflammation; lymphohistiocytic	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	100.0% **	0.0%	0.0%	100.0% **	0.0%	100.0% **
INTESTINE, CECUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	70.0%	100.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	10.0%	30.0%	0.0%	0.0%
INTESTINE, COLON;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	80.0%	80.0%	70.0%	70.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	10.0%	0.0%	20.0%	20.0%	10.0%	30.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	10.0%	30.0%	0.0%	0.0%
INTESTINE, DUODENUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INTESTINE, ILEUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	80.0%	80.0%	60.0%	100.0%	100.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	20.0%	30.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	10.0%	10.0%	20.0%	0.0%	10.0%	0.0%	0.0%
KIDNEY, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Congestion	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%
Basophilia; tubule	10.0%	10.0%	0.0%	20.0%	10.0%	20.0%	20.0%
Infiltration, Lymphocytic	20.0%	10.0%	30.0%	20.0%	0.0%	0.0%	20.0%
Mineralization	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	10.0%
Cyst; tubular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	10.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	20.0%
KIDNEY, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	0.0%	10.0%	10.0%	20.0%	20.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, RIGHT; (continued)							
Infiltration, Lymphocytic	0.0%	10.0%	30.0%	0.0%	10.0%	0.0%	0.0%
Inflammation; purulent; pelvis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Dilation; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration, Neutrophilic; subcapsular	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hematopoiesis; extramedullary	20.0%	40.0%	20.0%	30.0%	10.0%	10.0%	20.0%
Infiltration; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Necrosis	10.0%	0.0%	0.0%	10.0%	0.0%	10.0%	10.0%
Infiltration, Neutrophilic	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	50.0%	0.0%	50.0%	40.0%	20.0%	0.0%	30.0%
Vacuolation; hepatocellular	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Vacuolation; hepatocellular; periportal	0.0%	10.0%	10.0%	0.0%	80.0% **	10.0%	90.0% **
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Pigmentation; brown; kupffer cell	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LUNGS WITH BRONCHI;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	20.0%	30.0%	30.0%	20.0%	30.0%	40.0%	50.0%
Ossification	0.0%	10.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	40.0%	20.0%	50.0%	30.0%	20.0%	10.0%	30.0%
Hyperplasia; bronchial-associated lymphoid tissue	40.0%	60.0%	30.0%	60.0%	40.0%	30.0%	20.0%
Infiltration, Eosinophilic; perivascular	20.0%	0.0%	10.0%	20.0%	30.0%	10.0%	10.0%
Infiltration; foamy; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LYMPH NODE, CERVICAL;							
Examined	(8)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Histocytosis	100.0%	100.0%	90.0%	100.0%	100.0%	90.0%	80.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%	90.0%
LYMPH NODE, ILIAC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	90.0%	100.0%	90.0%	100.0%	100.0%	90.0%
Plasmacytosis	0.0%	50.0% *	70.0% **	90.0% **	80.0% **	60.0% *	100.0% **
Infiltration, Eosinophilic	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, ILIAC; (continued)							
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation	0.0%	50.0% *	0.0%	0.0%	50.0% *	40.0%	90.0% **
Increased Cellularity; germinal center	80.0%	90.0%	90.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, MESENTERIC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Increased Cellularity; germinal center	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, RENAL;							
Examined	(0)	(0)	(0)	(0)	(1)	(0)	(1)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Increased Cellularity; germinal center	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
MAMMARY GLANDS;							
Examined	(9)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	60.0%	100.0%
Inflammation; mixed; interstitium	0.0%	0.0%	0.0%	0.0%	20.0%	30.0%	0.0%
Inflammation; mixed; interstitium; lymphatic	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SKELETAL MUSCLE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	50.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	50.0% *
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	30.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NERVE, SCIATIC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	70.0%	100.0%	90.0%	30.0%	100.0%	0.0%
Inflammation; perineural	0.0%	30.0%	0.0%	10.0%	70.0% **	0.0%	100.0% **
Vacuolation	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, RIGHT;							
Examined	(10)	(7)	(10)	(9)	(10)	(10)	(9)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
OVARY, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVARY, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
PANCREAS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%
Atrophy; acinar cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; acinar cell	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
PARATHYROID, LEFT;							
Examined	(6)	(10)	(8)	(2)	(9)	(8)	(7)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PARATHYROID, LEFT; (continued)							
Fibrosis; interstitial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
PARATHYROID, RIGHT;							
Examined	(9)	(7)	(7)	(5)	(7)	(7)	(7)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(8)	(6)	(9)	(9)	(10)	(10)	(9)
Within Normal Limits	12.5%	16.7%	0.0%	0.0%	10.0%	0.0%	0.0%
Mineralization	0.0%	16.7%	22.2%	11.1%	0.0%	20.0%	11.1%
Inflammation, Granulomatous; follicular	0.0%	0.0%	11.1%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	87.5%	83.3%	100.0%	100.0%	90.0%	100.0%	100.0%
PITUITARY GLAND;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	70.0%
Cyst; pars distalis	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	30.0%
PROSTATE GLAND;							
Examined	(10)	(9)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	70.0%	88.9%	80.0%	80.0%	88.9%	90.0%	100.0%
Infiltration; mixed	0.0%	11.1%	10.0%	10.0%	0.0%	0.0%	0.0%
Inflammation; purulent	10.0%	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%
Infiltration, Lymphocytic	20.0%	0.0%	10.0%	0.0%	11.1%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(10)	(10)	(9)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SEMINAL VESICLES;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; fat	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
SKIN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	90.0%
Infiltration; mixed; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed; subcutaneous	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Necrosis; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Infiltration, Neutrophilic; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
SPINAL CORD;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SPINAL CORD; (continued)							
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SPLEEN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10.0%	0.0%	50.0%	10.0%	20.0%	50.0%	50.0%
Congestion	90.0%	100.0%	40.0%	90.0%	60.0%	50.0%	40.0%
Hematopoiesis; increased	0.0%	0.0%	30.0%	0.0%	20.0%	0.0%	20.0%
STOMACH, GLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10.0%	0.0%	50.0%	0.0%	0.0%	40.0%	0.0%
Infiltration, Eosinophilic	90.0%	90.0%	40.0%	100.0%	100.0%	50.0%	90.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Dilation; glandular	0.0%	20.0%	10.0%	10.0%	0.0%	10.0%	10.0%
Cyst	10.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; chief cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	10.0%	0.0%	0.0%	10.0%	10.0%
Infiltration, Neutrophilic; mucosa	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
STOMACH, NONGLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TESTIS, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
THYMUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	70.0%	30.0%	40.0%	50.0%	60.0%	50.0%	50.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	30.0%	70.0%	60.0%	50.0%	40.0%	50.0%	50.0%
THYROID, LEFT;							
Examined	(10)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	80.0%	100.0%	100.0%	100.0%	90.0%	100.0%
Cyst; keratinized	10.0%	20.0%	0.0%	0.0%	0.0%	10.0%	0.0%
TONGUE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TRACHEA; (continued)							
Within Normal Limits	50.0%	100.0%	70.0%	80.0%	80.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	30.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	10.0%	0.0%	20.0%	20.0%	20.0%	0.0%	0.0%
Pigmentation; brown; macrophage	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
URINARY BLADDER;							
Examined	(10)	(9)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	88.9%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	10.0%	11.1%	0.0%	0.0%	0.0%
UTERUS;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Dilation	-	-	-	-	-	-	-
VAGINA;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
ADRENAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	80.0%	70.0%	90.0%	90.0%	90.0%	80.0%
Dilation; vascular	0.0%	20.0%	20.0%	10.0%	10.0%	10.0%	20.0%
Hypertrophy; cortical	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	80.0%	100.0%	80.0%	100.0%	100.0%
Dilation; vascular	10.0%	10.0%	10.0%	0.0%	20.0%	0.0%	0.0%
Hypertrophy; cortical	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; cortical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
AORTA ABDOMINALIS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	90.0%	90.0%	100.0%	40.0%	100.0%	10.0%
Inflammation; mixed; surrounding tissue	0.0%	10.0%	10.0%	0.0%	60.0% *	0.0%	90.0% **
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
BONE, STERNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	100.0%	90.0%	100.0%	100.0%
Infiltration; mixed; surrounding tissue; muscle	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%	0.0%
BRAIN, BRAIN STEM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	80.0%	60.0%	70.0%	90.0%	90.0%	70.0%	88.9%
Keratinization; epithelial	20.0%	40.0%	30.0%	10.0%	10.0%	30.0%	11.1%
EPIDIDYMIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
EPIDIDYMIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
Infiltration; mixed	-	-	-	-	-	-	-
ESOPHAGUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EYE, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	70.0%	60.0%	70.0%	90.0%	60.0%	100.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	10.0%	10.0%	10.0%	0.0%
Infiltration; lymphohistiocytic	10.0%	10.0%	10.0%	10.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	20.0%	10.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%	70.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	30.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	80.0%	90.0%	90.0%	100.0%	90.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	10.0%	10.0%	0.0%	0.0%	10.0%	0.0%
INJECTION SITE I;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; intramuscular / interstitial	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Hemorrhage	10.0%	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%
Hemorrhage; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; granulomatous	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	30.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; dermis; subcutis	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; neutrophilic; dermis; epidermis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Inflammation; plasmacytic; perivascular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; vascular	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)							
Inflammation; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Necrosis; myofiber	0.0%	0.0%	10.0%	0.0%	10.0%	0.0%	0.0%
Necrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ulceration; epidermis	0.0%	30.0%	0.0%	0.0%	0.0%	20.0%	20.0%
Degeneration; myofiber	0.0%	90.0% **	90.0% **	100.0% **	100.0% **	90.0% **	100.0% **
Regeneration; muscle	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Foreign Material; hair	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	100.0% **	90.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Edema; intramuscular / interstitial	0.0%	100.0% **	80.0% **	90.0% **	100.0% **	100.0% **	100.0% **
Edema; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **	100.0% **
Hyperkeratosis; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	90.0% **	70.0% **	80.0% **	100.0% **	100.0% **	100.0% **
Scab; epidermal	0.0%	20.0%	0.0%	0.0%	0.0%	10.0%	10.0%
Pustule; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
INJECTION SITE II;							
Examined	(10)	(0)	(0)	(0)	(10)	(0)	(10)
Within Normal Limits	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Degeneration; myofiber	10.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Regeneration; muscle	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; epidermal	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	90.0% **
Scab; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Edema; subcutis	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Edema; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)							
Necrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; traumatic; myofiber	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Fibrosis; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Ulceration; epidermal	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; mixed; subcutis	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; mixed; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
INTESTINE, CECUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	90.0%	80.0%	80.0%	100.0%	90.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	20.0%	20.0%	0.0%	10.0%
INTESTINE, COLON;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	80.0%	80.0%	80.0%	70.0%	90.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	20.0%	20.0%	10.0%	30.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	20.0%	10.0%	0.0%	10.0%
INTESTINE, DUODENUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INTESTINE, ILEUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	80.0%	90.0%	50.0%	80.0%	90.0%	40.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	50.0% *	20.0%	0.0%	50.0% *
Hyperplasia; mucosa-associated lymphoid tissue	10.0%	20.0%	10.0%	0.0%	10.0%	10.0%	10.0%
KIDNEY, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	10.0%	0.0%	0.0%	10.0%	10.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	0.0%
Mineralization	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%	10.0%
Cyst; tubular	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, RIGHT; (continued)							
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; purulent; pelvis	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cast; hyaline; tubule	0.0%	10.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Dilation; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; subcapsular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(10)	(10)	(9)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hematopoiesis; extramedullary	30.0%	30.0%	10.0%	70.0%	50.0%	60.0%	50.0%
Infiltration; mixed	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	70.0%	10.0% *	30.0%	40.0%	0.0%	10.0% *	20.0%
Vacuolation; hepatocellular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Vacuolation; hepatocellular; periportal	0.0%	100.0% **	60.0% *	100.0% **	100.0% **	100.0% **	100.0% **
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; kupffer cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LUNGS WITH BRONCHI;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	80.0%	70.0%	50.0%	30.0%	30.0%	50.0%	20.0%
Ossification	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	20.0%	10.0%	10.0%	10.0%	0.0%
Hyperplasia; bronchial-associated lymphoid tissue	10.0%	20.0%	40.0%	40.0%	30.0%	50.0%	40.0%
Infiltration, Eosinophilic; perivascular	10.0%	0.0%	10.0%	40.0%	20.0%	0.0%	60.0%
Infiltration; foamy; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LYMPH NODE, CERVICAL;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	90.0%	90.0%	100.0%	100.0%	100.0%	80.0%	90.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	20.0%	10.0%	0.0%
Hemorrhage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	80.0%	100.0%	100.0%	90.0%	100.0%	100.0%	80.0%
LYMPH NODE, ILIAC;							
Examined	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	90.0%	90.0%	60.0%	70.0%	100.0%	100.0%	90.0%
Plasmacytosis	0.0%	30.0%	70.0% **	80.0% **	100.0% **	70.0% **	100.0% **
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	11.1%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, ILIAC; (continued)							
Hemorrhage; acute	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation	0.0%	60.0% *	30.0%	0.0%	77.8% **	70.0% **	60.0% *
Increased Cellularity; germinal center	30.0%	80.0%	100.0% **	80.0%	100.0% **	100.0% **	100.0% **
LYMPH NODE, MESENTERIC;							
Examined	(9)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Eosinophilic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%
LYMPH NODE, RENAL;							
Examined	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plasmacytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
MAMMARY GLANDS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	70.0%	100.0%	90.0%	70.0%	100.0%
Inflammation; mixed; interstitium	0.0%	0.0%	30.0%	0.0%	10.0%	30.0%	0.0%
Inflammation; mixed; interstitium; lymphatic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SKELETAL MUSCLE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	90.0%	100.0%	100.0%	70.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration; mixed	0.0%	10.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Necrosis; myofiber	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NERVE, SCIATIC;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	80.0%	60.0%	0.0%	100.0%	0.0%
Inflammation; perineural	0.0%	0.0%	10.0%	40.0%	100.0% **	0.0%	100.0% **
Vacuolation	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, LEFT;							
Examined	(10)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	80.0%	90.0%	100.0%	100.0%	90.0%	90.0%
Hemorrhage; acute	0.0%	20.0%	0.0%	0.0%	0.0%	10.0%	10.0%
Pigmentation; brown; macrophage	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
OPTIC NERVE, RIGHT;							
Examined	(10)	(9)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	88.9%	90.0%	90.0%	100.0%	90.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	11.1%	0.0%	0.0%	0.0%	10.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
OVARY, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVARY, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, LEFT;							
Examined	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PANCREAS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	90.0%	90.0%	100.0%	100.0%	100.0%
Atrophy; acinar cell	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Hyperplasia; acinar cell	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
PARATHYROID, LEFT;							
Examined	(10)	(10)	(6)	(9)	(7)	(10)	(4)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	85.7%	100.0%	75.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PARATHYROID, LEFT; (continued)							
Fibrosis; interstitial	0.0%	10.0%	0.0%	0.0%	14.3%	0.0%	25.0%
PARATHYROID, RIGHT;							
Examined	(9)	(10)	(6)	(9)	(6)	(8)	(7)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(10)	(6)	(8)	(8)	(8)	(7)	(9)
Within Normal Limits	0.0%	0.0%	12.5%	0.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	14.3%	11.1%
Inflammation, Granulomatous; follicular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	87.5%	100.0%	100.0%	100.0%	100.0%
PITUITARY GLAND;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	100.0%	90.0%	100.0%	100.0%	100.0%	90.0%	100.0%
Cyst; pars distalis	0.0%	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%
PROSTATE GLAND;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration; mixed	-	-	-	-	-	-	-
Inflammation; purulent	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(9)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SEMINAL VESICLES;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration; mixed; surrounding tissue; fat	-	-	-	-	-	-	-
SKIN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	70.0%	100.0%	40.0%
Infiltration; mixed; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	30.0%	0.0%	60.0% *
Infiltration; mixed; subcutaneous	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Necrosis; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Neutrophilic; muscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SPINAL CORD;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SPINAL CORD; (continued)							
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%
SPLEEN;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	10.0%	60.0%	10.0%	30.0%	30.0%	0.0%
Congestion	100.0%	90.0%	30.0% **	90.0%	40.0% *	70.0%	70.0%
Hematopoiesis; increased	0.0%	0.0%	20.0%	0.0%	70.0% **	0.0%	80.0% **
STOMACH, GLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0.0%	30.0%	50.0%	0.0%	0.0%	60.0%	10.0%
Infiltration, Eosinophilic	100.0%	50.0% *	40.0% *	100.0%	100.0%	30.0% **	80.0%
Infiltration, Lymphocytic	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%	0.0%
Dilation; glandular	0.0%	10.0%	20.0%	10.0%	0.0%	10.0%	10.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; chief cell	0.0%	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	10.0%	0.0%	0.0%	10.0%	0.0%	0.0%
Infiltration, Neutrophilic; mucosa	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
STOMACH, NONGLANDULAR;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TESTIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
THYMUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	30.0%	20.0%	80.0%	60.0%	50.0%	50.0%	20.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%
Hemorrhage; acute	70.0%	80.0%	20.0%	40.0%	50.0%	40.0%	80.0%
THYROID, LEFT;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	70.0%	90.0%	100.0%	90.0%	100.0%	100.0%
Cyst; keratinized	10.0%	30.0%	10.0%	0.0%	10.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	88.9%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	11.1%	0.0%
TONGUE;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	90.0%	100.0%	100.0%	100.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TRACHEA; (continued)							
Within Normal Limits	80.0%	90.0%	90.0%	70.0%	90.0%	90.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	20.0%	0.0%	10.0%	30.0%	10.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	10.0%	0.0%	0.0%	0.0%	10.0%	0.0%
URINARY BLADDER;							
Examined	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	90.0%	100.0%	100.0%	100.0%	88.9%	100.0%	90.0%
Infiltration, Lymphocytic	10.0%	0.0%	0.0%	0.0%	11.1%	0.0%	10.0%
UTERUS;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	100.0%	70.0%	60.0%	80.0%	100.0%	100.0%	90.0%
Dilation	0.0%	30.0%	40.0%	20.0%	0.0%	0.0%	10.0%
VAGINA;							
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	70.0%	50.0%	50.0%	90.0%	80.0%	60.0%	70.0%
Keratinization; epithelial	30.0%	50.0%	50.0%	10.0%	20.0%	40.0%	30.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ADRENAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	40.0%	80.0%	40.0%	60.0%	80.0%	60.0%
Dilation; vascular	20.0%	60.0%	20.0%	60.0%	40.0%	20.0%	40.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	60.0%	100.0%	100.0%	80.0%	60.0%	60.0%
Dilation; vascular	20.0%	40.0%	0.0%	0.0%	20.0%	40.0%	40.0%
AORTA ABDOMINALIS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%
Infiltration, Lymphocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Infiltration; lymphohistiocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, STERNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
BRAIN, BRAIN STEM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-
Cyst; keratinized	-	-	-	-	-	-	-
EPIDIDYMIS, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	0.0%	20.0%	20.0%	40.0%	20.0%	60.0%
Infiltration, Lymphocytic	80.0%	100.0%	80.0%	80.0%	60.0%	80.0%	40.0%
EPIDIDYMIS, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	40.0%	20.0%	0.0%	20.0%	40.0%	0.0%	40.0%
Infiltration, Lymphocytic	60.0%	80.0%	100.0%	80.0%	60.0%	100.0%	60.0%
Oligospermia	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ESOPHAGUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HARDERIAN GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	60.0%	80.0%	80.0%	100.0%	100.0%	60.0%
Infiltration; lymphohistiocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
HEART; (continued)							
Infiltration, Lymphocytic	0.0%	20.0%	20.0%	20.0%	0.0%	0.0%	40.0%
INJECTION SITE I;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	80.0%	0.0%
Fibrosis; intramuscular / interstitial	0.0%	20.0%	60.0%	80.0% *	80.0% *	0.0%	80.0% *
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	20.0%	100.0% **
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	40.0%	40.0%	100.0% **	80.0% *	0.0%	60.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	100.0% **	80.0% *	100.0% **	100.0% **	20.0%	100.0% **
Mineralization; inter- / perimuscular	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Multinucleated Macrophages; inter- / perimuscular	0.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;							
Examined	(5)	(1)	(0)	(0)	(5)	(0)	(5)
Within Normal Limits	100.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fibrosis; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Fibrosis; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	80.0% *	0.0%	80.0% *
Fibrosis; dermis; subcutis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	100.0% **
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	100.0% **	0.0%	80.0% *
INTESTINE, CECUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INTESTINE, COLON;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	20.0%	100.0%	60.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INTESTINE, COLON; (continued)							
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	20.0%	80.0% *	0.0%	40.0%	0.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INTESTINE, DUODENUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, ILEUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	60.0%	60.0%	100.0%	60.0%	80.0%	60.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	20.0%	40.0%	40.0%	0.0%	40.0%	20.0%	40.0%
Nematodiasis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	20.0%	0.0%	20.0%	0.0%	0.0%	20.0%	0.0%
Infiltration, Lymphocytic	40.0%	0.0%	20.0%	20.0%	20.0%	0.0%	20.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
KIDNEY, LEFT; (continued)							
Degeneration; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	40.0%
Infiltration, Lymphocytic	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%
Cast; hyaline; tubule	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Pyelonephritis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Congestion	100.0%	100.0%	80.0%	100.0%	100.0%	80.0%	100.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Necrosis	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%	0.0%
Infiltration, Lymphocytic	80.0%	100.0%	100.0%	80.0%	80.0%	40.0%	40.0%
Vacuolation; hepatocellular	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LIVER; (continued)							
Vacuolation; hepatocellular; periportal	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LUNGS WITH BRONCHI;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	20.0%	60.0%	20.0%	40.0%	20.0%	40.0%
Ossification	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	20.0%	0.0%	40.0%	20.0%	60.0%	40.0%
Hyperplasia; bronchial-associated lymphoid tissue	60.0%	60.0%	40.0%	60.0%	40.0%	60.0%	20.0%
Infiltration, Eosinophilic; perivascular	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; macrophage; alveolus	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LYMPH NODE, CERVICAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	60.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, ILIAC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%
Plasmacytosis	0.0%	0.0%	0.0%	40.0%	60.0%	0.0%	20.0%
Infiltration; macrophage	0.0%	0.0%	20.0%	20.0%	100.0% **	60.0%	100.0% **
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, MESENTERIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
MAMMARY GLANDS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SKELETAL MUSCLE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NERVE, SCIATIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	60.0%
Inflammation; perineural	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	40.0%
OPTIC NERVE, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
OPTIC NERVE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	80.0%	80.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
OVARY, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVARY, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
OVIDUCT, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
PANCREAS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PARATHYROID, LEFT;							
Examined	(2)	(2)	(3)	(5)	(5)	(4)	(4)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PARATHYROID, RIGHT;							
Examined	(4)	(3)	(4)	(3)	(4)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(4)	(3)	(4)	(5)	(5)	(4)	(3)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	0.0%
Mineralization	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Granulomatous; follicular	25.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	75.0%	100.0%
PITUITARY GLAND;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; pars distalis	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cyst; pars intermedia	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
PROSTATE GLAND;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	40.0%	20.0%	80.0%	40.0%	60.0%
Inflammation; purulent	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%	0.0%
Infiltration, Lymphocytic	0.0%	20.0%	60.0%	80.0% *	0.0%	40.0%	40.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(5)	(5)	(5)	(5)	(4)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SEMINAL VESICLES;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SKIN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPINAL CORD;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPLEEN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	40.0%	20.0%	60.0%	60.0%	60.0%	60.0%	60.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SPLEEN; (continued)							
Congestion	60.0%	80.0%	40.0%	40.0%	40.0%	40.0%	40.0%
STOMACH, GLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	40.0%	20.0%	20.0%	0.0%
Infiltration, Eosinophilic	100.0%	100.0%	100.0%	60.0%	80.0%	80.0%	100.0%
Dilation; glandular	0.0%	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%
Cyst	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
STOMACH, NONGLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Spermatid Giant Cells	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dilation; tubular	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
TESTIS, RIGHT;							
Examined	(5)	(4)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Dilation; tubular	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration; lymphoplasmacytic	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spermatocoele	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
THYMUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	80.0%	60.0%	80.0%	60.0%	40.0%	60.0%
Hemorrhage; acute	40.0%	20.0%	40.0%	20.0%	40.0%	60.0%	40.0%
THYROID, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TONGUE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%
Granuloma	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Granuloma; hair	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%	0.0%
URINARY BLADDER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	MALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
URINARY BLADDER; (continued)							
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
UTERUS;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Dilation	-	-	-	-	-	-	-
VAGINA;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Keratinization; epithelial	-	-	-	-	-	-	-

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ADRENAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	40.0%	80.0%	40.0%	60.0%	100.0%	80.0%	80.0%
Dilation; vascular	60.0%	20.0%	60.0%	40.0%	0.0%	20.0%	20.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ADRENAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	100.0%	60.0%	100.0%	100.0%	80.0%
Dilation; vascular	20.0%	20.0%	0.0%	40.0%	0.0%	0.0%	20.0%
AORTA ABDOMINALIS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%
Infiltration, Lymphocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; lymphohistiocytic; surrounding tissue	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
BONE MARROW, OS FEMORIS WITH JOINT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BONE, STERNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
BRAIN, BRAIN STEM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBELLUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
BRAIN, CEREBRUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
CERVIX;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	40.0%	60.0%	20.0%	40.0%	60.0%	60.0%
Keratinization; epithelial	20.0%	60.0%	40.0%	80.0%	60.0%	40.0%	40.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
EPIDIDYMIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
Oligospermia	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ESOPHAGUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
EYE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HARDERIAN GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	80.0%	100.0%	80.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Inflammation, Chronic	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
HARDERIAN GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	80.0%	80.0%	100.0%	100.0%	80.0%	80.0%
Infiltration, Lymphocytic	20.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%	20.0%
Inflammation, Chronic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
HEART;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
HEART; (continued)							
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
INJECTION SITE I;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%
Fibrosis; intramuscular / interstitial	0.0%	60.0%	20.0%	80.0% *	20.0%	0.0%	80.0% *
Fibrosis; inter- / perimuscular	0.0%	100.0% **	100.0% **	100.0% **	100.0% **	80.0% *	80.0% *
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	80.0% *	20.0%	80.0% *	20.0%	0.0%	80.0% *
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	80.0% *	60.0%	100.0% **	80.0% *	60.0%	80.0% *
Mineralization; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Multinucleated Macrophages; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
INJECTION SITE II;							
Examined	(5)	(1)	(0)	(0)	(5)	(0)	(5)
Within Normal Limits	100.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
Fibrosis; inter- / perimuscular	0.0%	100.0%	0.0%	0.0%	80.0% *	0.0%	80.0% *
Fibrosis; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	40.0%
Fibrosis; dermis; subcutis	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation; lymphohistiocytic; inter- / perimuscular	0.0%	0.0%	0.0%	0.0%	60.0%	0.0%	80.0% *
Inflammation; lymphohistiocytic; intramuscular / interstitial	0.0%	0.0%	0.0%	0.0%	40.0%	0.0%	60.0%
INTESTINE, CECUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	80.0%	80.0%	100.0%	100.0%	100.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	20.0%	20.0%	20.0%	0.0%	0.0%	0.0%
INTESTINE, COLON;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	80.0%	80.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INTESTINE, COLON; (continued)							
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	20.0%	0.0%	0.0%	20.0%	0.0%
Infiltration, Eosinophilic; increased	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
INTESTINE, DUODENUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, ILEUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, JEJUNUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
INTESTINE, RECTUM;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	80.0%	100.0%	80.0%	100.0%	100.0%	60.0%
Infiltration, Eosinophilic; increased	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%	20.0%
Nematodiasis	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Basophilia; tubule	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	20.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Cast; hyaline; tubule	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
KIDNEY, LEFT; (continued)							
Degeneration; hyaline; tubule	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
KIDNEY, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Basophilia; tubule	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%	0.0%
Cast; hyaline; tubule	20.0%	0.0%	20.0%	20.0%	0.0%	0.0%	0.0%
Mineralization	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Pyelonephritis	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Inflammation, Chronic; interstitial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
LACRIMAL GLAND, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LACRIMAL GLAND, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LIVER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Congestion	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	20.0%
Necrosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	40.0%	60.0%	80.0%	40.0%	40.0%	80.0%	0.0%
Vacuolation; hepatocellular	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LIVER; (continued)							
Vacuolation; hepatocellular; periportal	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
LUNGS WITH BRONCHI;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	20.0%	80.0%	40.0%	60.0%	100.0%	40.0%
Ossification	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	20.0%	40.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; bronchial-associated lymphoid tissue	20.0%	40.0%	0.0%	60.0%	20.0%	0.0%	20.0%
Infiltration, Eosinophilic; perivascular	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	40.0%
Infiltration; macrophage; alveolus	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; mixed	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
LYMPH NODE, CERVICAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	80.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
LYMPH NODE, ILIAC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	100.0%	100.0%	100.0%	60.0%	100.0%	100.0%	100.0%
Plasmacytosis	0.0%	60.0%	60.0%	60.0%	100.0% **	20.0%	100.0% **
Infiltration; macrophage	0.0%	60.0%	0.0%	60.0%	100.0% **	100.0% **	100.0% **
Increased Cellularity; germinal center	80.0%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, MESENTERIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erythrophagocytosis	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Histocytosis	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	60.0%
MAMMARY GLANDS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SKELETAL MUSCLE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	80.0%
Infiltration; lymphohistiocytic	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%
NERVE, SCIATIC;							
Examined	(5)	(5)	(5)	(5)	(5)	(4)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%	80.0%
Inflammation; perineural	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
OPTIC NERVE, LEFT;							
Examined	(4)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
OPTIC NERVE, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Pigmentation; brown; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Hemorrhage; acute	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration; foamy; macrophage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
OVARY, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVARY, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, LEFT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
OVIDUCT, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(4)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PANCREAS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	0.0%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PARATHYROID, LEFT;							
Examined	(4)	(5)	(1)	(4)	(3)	(4)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PARATHYROID, RIGHT;							
Examined	(3)	(5)	(4)	(4)	(2)	(4)	(4)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
PEYERS PATCHES;							
Examined	(5)	(5)	(5)	(5)	(4)	(4)	(5)
Within Normal Limits	0.0%	0.0%	0.0%	40.0%	0.0%	0.0%	20.0%
Mineralization	0.0%	0.0%	20.0%	0.0%	25.0%	0.0%	0.0%
Inflammation, Granulomatous; follicular	0.0%	0.0%	20.0%	20.0%	25.0%	0.0%	0.0%
Increased Cellularity; germinal center	100.0%	100.0%	100.0%	60.0%	100.0%	100.0%	80.0%
PITUITARY GLAND;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	100.0%	100.0%	100.0%
Cyst; pars distalis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cyst; pars intermedia	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
PROSTATE GLAND;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Inflammation; purulent	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SALIVARY GLANDS, MANDIBULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, SUBLINGUAL;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SALIVARY GLANDS, PAROTIS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SEMINAL VESICLES;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Infiltration, Lymphocytic	-	-	-	-	-	-	-
SKIN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPINAL CORD;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
SPLEEN;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	60.0%	40.0%	20.0%	40.0%	60.0%	0.0%	40.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SPLEEN; (continued)							
Congestion	40.0%	60.0%	80.0%	60.0%	40.0%	100.0%	60.0%
STOMACH, GLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	20.0%	0.0%	20.0%	0.0%	0.0%	20.0%	40.0%
Infiltration, Eosinophilic	80.0%	100.0%	80.0%	100.0%	100.0%	80.0%	60.0%
Dilation; glandular	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%
Cyst	20.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
Hyperplasia; mucosa-associated lymphoid tissue	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%
STOMACH, NONGLANDULAR;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
TESTIS, LEFT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Spermatid Giant Cells	-	-	-	-	-	-	-
Dilation; tubular	-	-	-	-	-	-	-
TESTIS, RIGHT;							
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	-	-	-	-	-	-	-
Dilation; tubular	-	-	-	-	-	-	-
Infiltration; lymphoplasmacytic	-	-	-	-	-	-	-
Spermatocoele	-	-	-	-	-	-	-

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
THYMUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	60.0%	80.0%	60.0%	100.0%	60.0%	80.0%
Hemorrhage; acute	20.0%	40.0%	20.0%	40.0%	0.0%	40.0%	20.0%
THYROID, LEFT;							
Examined	(5)	(5)	(4)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Cyst; keratinized	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
THYROID, RIGHT;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	100.0%	100.0%	100.0%	80.0%	100.0%
Cyst; keratinized	0.0%	20.0%	0.0%	0.0%	0.0%	20.0%	0.0%
TONGUE;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	100.0%	100.0%	100.0%	80.0%	100.0%
Granuloma	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%
Granuloma; hair	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TRACHEA;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	80.0%	80.0%	100.0%	100.0%	100.0%	80.0%
Infiltration; lymphohistiocytic	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infiltration, Lymphocytic	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	20.0%
URINARY BLADDER;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Incidence

Observations: Neo-Plastic and Non Neo-Plastic	FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)
URINARY BLADDER; (continued)							
Within Normal Limits	80.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Infiltration, Lymphocytic	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
UTERUS;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	100.0%	100.0%	80.0%	100.0%	80.0%	100.0%	100.0%
Dilation	0.0%	0.0%	20.0%	0.0%	20.0%	0.0%	0.0%
VAGINA;							
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	80.0%	40.0%	60.0%	20.0%	20.0%	60.0%	40.0%
Keratinization; epithelial	20.0%	60.0%	40.0%	80.0%	80.0%	40.0%	60.0%

Fisher's Two-Tailed Exact Test Performed: * = 5% Significance Level ** = 1% Significance Level.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
ADRENAL GLAND, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	9	6	9	9	9	8	10	8	7	9	9	9	8
Dilation; vascular	(1)	(1)	(4)	(1)	(1)	(1)	(1)	(0)	(2)	(2)	(1)	(1)	(1)	(2)
minimal	1	1	4	1	1	1	1	0	2	2	1	1	1	2
Hypertrophy; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Vacuolation; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
ADRENAL GLAND, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	9	7	10	8	10	8	9	9	8	10	8	10	10
Dilation; vascular	(1)	(1)	(3)	(0)	(2)	(0)	(1)	(1)	(1)	(1)	(0)	(2)	(0)	(0)
minimal	1	1	3	0	2	0	1	1	1	1	0	2	0	0
Hypertrophy; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Vacuolation; cortical	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
AORTA ABDOMINALIS;														
Examined	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	9	10	10	10	10	10	10	10	10	10	10	10	10
Not Examined: NOT PRESENT	0	1	0	0	0	0	0	0	0	0	0	0	0	0
BONE, OS FEMORIS WITH JOINT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	6	10	8	10	9	9	10	4	10	1
Inflammation; mixed; surrounding tissue	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(1)	(0)	(4)	(0)	(3)
minimal	0	0	0	0	1	0	0	0	1	1	0	2	0	0
mild	0	0	0	0	1	0	0	0	0	0	0	2	0	3
Inflammation; mixed; surrounding tissue; focal	(0)	(0)	(0)	(0)	(2)	(0)	(2)	(0)	(0)	(0)	(0)	(2)	(0)	(6)
mild	0	0	0	0	1	0	2	0	0	0	0	1	0	4
moderate	0	0	0	0	1	0	0	0	0	0	0	1	0	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
BONE MARROW, OS FEMORIS WITH JOINT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	0	0	0	0	0	0	10	0	0	0	0	0	0
Increased Cellularity	(0)	(10)	(10)	(10)	(10)	(10)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	10	10	10	10	10	10	0	10	10	10	10	10	10
BONE, STERNUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	9	9	10	10	10	9	10	9	10	10
Not Examined: NO SECTION	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; surrounding tissue; muscle; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	1	0	0
Infiltration; mixed; surrounding tissue; muscle; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
BRAIN, BRAIN STEM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BRAIN, CEREBELLUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BRAIN, CEREBRUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
CERVIX;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	-	-	-	-	-	-	-	8	6	7	9	9	7	8
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	0	0	1
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(2)	(4)	(3)	(1)	(1)	(3)	(1)
minimal	-	-	-	-	-	-	-	0	0	0	0	1	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
CERVIX; (continued)														
mild	-	-	-	-	-	-	-	2	4	3	1	0	3	1
EPIDIDYMIS, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	3	2	1	7	3	4	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	1	0	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(7)	(8)	(9)	(3)	(6)	(6)	(8)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	7	8	9	3	6	6	8	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	3	1	3	4	2	4	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	0	0	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(7)	(9)	(7)	(5)	(8)	(6)	(9)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	7	9	7	5	8	6	9	-	-	-	-	-	-	-
Infiltration; mixed; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	1	0	0	0	-	-	-	-	-	-	-
ESOPHAGUS;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
EYE, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	9	10	10	10	10	10	10
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
EYE, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	9	9	10	9	9	7	6	7	9	6	10
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(2)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	1	1	0	0	0	2	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	1	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(1)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	1	0	0	0	0
mild	0	0	0	0	0	0	0	1	0	0	1	0	0	0
Infiltration; lymphohistiocytic; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	1	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Inflammation; granulomatous; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Inflammation; purulent; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Inflammation, Chronic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
HARDERIAN GLAND, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	8	10	9	10	8	7	10	10	10	9	10	10	10	7
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	1	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	1	0	0	0	0	0	0	0	0	0
Necrosis; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
HARDERIAN GLAND, RIGHT; (continued)														
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)
minimal	0	0	0	0	0	2	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Inflammation, Chronic; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
HEART;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	9	9	8	9	10	10	10	8	9	9	10	9	10
Infiltration; lymphohistiocytic; focal	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	1	0	0	0	0	0
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	1	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	1	0	0	0	1	0	0	0	1	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	1	0	0	0	0
INJECTION SITE I;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	4	0	0	0	0	1	0	5	0	0	0	0	0	0
Fibrosis; intramuscular / interstitial	(0)	(9)	(10)	(9)	(9)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	1	0	0	1	0	0	0	0	0	0	1	0	0
mild	0	8	10	9	8	8	10	0	10	10	10	9	10	10
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Fibrosis; inter- / perimuscular	(0)	(10)	(10)	(9)	(10)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
mild	0	10	10	9	10	8	10	0	10	10	10	10	10	10
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
Hemorrhage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(1)	(0)	(1)	(0)
mild	0	0	0	0	0	0	1	1	0	0	0	0	1	0
moderate	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Hemorrhage; subcutis; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Inflammation; granulomatous; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; lymphocytic; inter- / perimuscular; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Inflammation; lymphohistiocytic; focal	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; lymphohistiocytic; multifocal	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	4	0	0	0	0	0	0	2	0	0	0	0	0	0
Inflammation; lymphohistiocytic; dermis; subcutis; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; neutrophilic; dermis; epidermis; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Inflammation; plasmacytic; perivascular; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Inflammation; vascular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
moderate	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Inflammation; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; mixed; subcutis	(0)	(9)	(10)	(10)	(10)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
mild	0	0	0	1	2	0	0	0	0	0	0	0	0	0
moderate	0	9	10	7	8	9	9	0	10	10	10	10	10	10
marked	0	0	0	2	0	0	1	0	0	0	0	0	0	0
Inflammation; mixed; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
Inflammation; mixed; intramuscular / interstitial	(0)	(9)	(10)	(10)	(5)	(4)	(5)	(0)	(10)	(10)	(9)	(8)	(3)	(9)
minimal	0	1	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	4	8	1	3	4	4	0	8	4	4	8	3	9
moderate	0	4	2	9	1	0	1	0	2	6	5	0	0	0
Inflammation; mixed; intramuscular / interstitial; multifocal	(0)	(0)	(0)	(0)	(4)	(5)	(5)	(0)	(0)	(0)	(1)	(2)	(7)	(1)
moderate	0	0	0	0	4	5	5	0	0	0	1	2	7	1
Inflammation; mixed; inter- / perimuscular	(0)	(10)	(10)	(10)	(9)	(9)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	3	0	1	0	0	0	0	0	0	0	0	0	0
moderate	0	7	10	6	8	9	9	0	10	7	9	10	8	10
marked	0	0	0	3	0	0	1	0	0	3	1	0	2	0
Inflammation; mixed; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Necrosis; myofiber; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Necrosis; myofiber; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Necrosis; dermis; subcutis; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Ulceration; epidermis; focal	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(1)	(2)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
moderate	0	1	1	0	0	0	0	0	3	0	0	0	1	0
Ulceration; epidermis; multifocal	(0)	(1)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	1	0	0	0	1	0	0	0	0	0	0	0	0
moderate	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Degeneration; myofiber	(0)	(9)	(9)	(9)	(10)	(8)	(10)	(0)	(9)	(9)	(10)	(10)	(9)	(10)
minimal	0	2	0	1	1	0	0	0	0	0	2	2	0	0
mild	0	7	9	8	9	7	10	0	9	9	8	8	4	10

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
moderate	0	0	0	0	0	1	0	0	0	0	0	0	5	0
Degeneration; myofiber; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Regeneration; muscle; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Foreign Material; hair; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Edema; subcutis	(0)	(6)	(10)	(9)	(8)	(9)	(10)	(0)	(10)	(9)	(10)	(10)	(10)	(10)
mild	0	1	1	4	1	0	1	0	0	1	4	2	0	2
moderate	0	5	9	4	7	6	7	0	10	6	6	8	5	7
marked	0	0	0	1	0	3	2	0	0	2	0	0	5	1
Edema; intramuscular / interstitial	(0)	(2)	(7)	(8)	(8)	(9)	(10)	(0)	(10)	(8)	(9)	(10)	(10)	(10)
minimal	0	1	6	2	1	1	0	0	8	1	2	1	1	0
mild	0	1	1	6	7	8	10	0	2	7	7	9	9	10
Edema; inter- / perimuscular	(0)	(7)	(10)	(10)	(8)	(10)	(10)	(0)	(10)	(10)	(10)	(10)	(10)	(11)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
mild	0	2	5	3	0	2	0	0	1	0	1	2	1	0
moderate	0	4	5	6	8	6	6	0	9	8	8	6	8	6
marked	0	1	0	1	0	2	4	0	0	1	1	2	1	5
Hyperkeratosis; epidermal; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia; epidermal	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	2	0	0	0	0	0	0	0	0	0	0	0	0
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia; epidermal; widespread	(0)	(4)	(9)	(9)	(10)	(9)	(9)	(0)	(9)	(7)	(8)	(10)	(10)	(10)
mild	0	0	2	5	3	0	2	0	0	3	7	1	0	1
moderate	0	4	7	4	7	9	7	0	9	4	1	9	10	9
Hyperplasia; epidermal; focal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Scab; epidermal; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(1)
minimal	0	0	1	0	0	0	0	0	1	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Scab; epidermal; multifocal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	1	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE I; (continued)														
Pustule; epidermal; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
INJECTION SITE II;														
Examined	(10)	(4)	(0)	(0)	(10)	(0)	(10)	(10)	(0)	(0)	(0)	(10)	(0)	(10)
Within Normal Limits	5	0	0	0	0	0	0	5	0	0	0	0	0	0
Degeneration; myofiber	(0)	(3)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
minimal	0	0	0	0	0	0	0	0	0	0	0	2	0	2
mild	0	3	0	0	10	0	10	0	0	0	0	8	0	8
Degeneration; myofiber; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Regeneration; muscle	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Regeneration; muscle; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Hyperplasia; epidermal; widespread	(0)	(2)	(0)	(0)	(10)	(0)	(7)	(0)	(0)	(0)	(0)	(10)	(0)	(9)
mild	0	0	0	0	1	0	1	0	0	0	0	2	0	3
moderate	0	2	0	0	9	0	6	0	0	0	0	8	0	6
Hyperplasia; epidermal; focal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Scab; epidermal; focal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Edema; subcutis	(0)	(2)	(0)	(0)	(10)	(0)	(11)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	2
mild	0	0	0	0	3	0	1	0	0	0	0	1	0	1
moderate	0	2	0	0	4	0	6	0	0	0	0	9	0	4
marked	0	0	0	0	3	0	3	0	0	0	0	0	0	3
Edema; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Edema; inter- / perimuscular	(0)	(2)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	1	0	0	0	0	1	0	0	0	0	0	0	2
moderate	0	1	0	0	7	0	4	0	0	0	0	9	0	4
marked	0	0	0	0	3	0	5	0	0	0	0	1	0	4
Edema; intramuscular / interstitial	(0)	(0)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)														
minimal	0	0	0	0	0	0	1	0	0	0	0	1	0	2
mild	0	0	0	0	10	0	9	0	0	0	0	8	0	8
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Necrosis; myofiber; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis; myofiber; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Necrosis; dermis; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis; traumatic; myofiber; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis; subcutis	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Fibrosis; inter- / perimuscular	(0)	(2)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	2	0	0	10	0	10	0	0	0	0	10	0	10
Fibrosis; inter- / perimuscular; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis; intramuscular / interstitial	(0)	(2)	(0)	(0)	(10)	(0)	(9)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	2	0	0	10	0	9	0	0	0	0	10	0	10
Fibrosis; intramuscular / interstitial; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Ulceration; epidermal; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Inflammation; lymphohistiocytic; focal	(3)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	0	0	0	0	0	2	0	0	0	0	0	0
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; lymphohistiocytic; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	2	0	0	0	0	0	0
Inflammation; mixed; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INJECTION SITE II; (continued)														
Inflammation; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; mixed; subcutis	(0)	(3)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
mild	0	0	0	0	1	0	0	0	0	0	0	1	0	2
moderate	0	3	0	0	9	0	10	0	0	0	0	9	0	8
Inflammation; mixed; subcutis; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; inter- / perimuscular	(0)	(3)	(0)	(0)	(10)	(0)	(10)	(0)	(0)	(0)	(0)	(10)	(0)	(10)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
moderate	0	2	0	0	10	0	10	0	0	0	0	10	0	10
Inflammation; mixed; inter- / perimuscular; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; intramuscular / interstitial	(0)	(3)	(0)	(0)	(5)	(0)	(4)	(0)	(0)	(0)	(0)	(6)	(0)	(9)
mild	0	2	0	0	5	0	4	0	0	0	0	6	0	9
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; intramuscular / interstitial; multifocal	(0)	(1)	(0)	(0)	(5)	(0)	(6)	(0)	(0)	(0)	(0)	(4)	(0)	(1)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
moderate	0	0	0	0	5	0	6	0	0	0	0	4	0	1
INTESTINE, CECUM;														
Examined.....	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits.....	10	10	10	8	7	10	10	10	10	9	8	8	10	9
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	2	0	0	0	0	0	1	0	0	0	0
Infiltration, Eosinophilic; increased ...	(0)	(0)	(0)	(1)	(3)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(0)	(1)
minimal	0	0	0	1	3	0	0	0	0	0	2	2	0	1
INTESTINE, COLON;														
Examined.....	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
INTESTINE, COLON; (continued)														
Within Normal Limits	9	10	8	8	7	7	10	10	10	8	8	8	7	9
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(0)	(2)	(2)	(1)	(3)	(0)	(0)	(0)	(2)	(2)	(1)	(3)	(0)
minimal	0	0	1	0	0	1	0	0	0	0	0	0	1	0
mild	0	0	1	2	1	2	0	0	0	2	2	1	1	0
moderate	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(1)	(3)	(0)	(0)	(0)	(0)	(0)	(2)	(1)	(0)	(1)
minimal	0	0	0	1	3	0	0	0	0	0	2	1	0	1
INTESTINE, DUODENUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
INTESTINE, ILEUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
INTESTINE, JEJUNUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
INTESTINE, RECTUM;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	9	8	8	6	10	10	9	8	9	5	8	9	4
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(2)	(3)	(0)	(0)	(0)	(0)	(0)	(5)	(2)	(0)	(5)
minimal	0	0	0	1	3	0	0	0	0	0	5	2	0	5
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(1)	(2)	(0)	(1)	(0)	(0)	(1)	(2)	(1)	(0)	(1)	(1)	(1)
minimal	0	0	1	0	0	0	0	1	0	1	0	0	1	1
mild	1	1	1	0	1	0	0	0	2	0	0	1	0	0
KIDNEY, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, LEFT; (continued)														
Within Normal Limits	1	0	0	0	0	0	1	0	0	0	0	0	0	0
Congestion	(9)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
mild	2	4	5	4	3	1	1	3	5	5	3	5	8	5
moderate	7	6	5	6	7	9	8	7	5	5	7	5	2	5
Basophilia; tubule; focal	(1)	(1)	(0)	(1)	(1)	(2)	(1)	(1)	(0)	(0)	(1)	(1)	(0)	(0)
minimal	0	1	0	1	1	1	1	1	0	0	1	1	0	0
mild	1	0	0	0	0	1	0	0	0	0	0	0	0	0
Basophilia; tubule; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	1	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(0)	(1)	(1)	(1)	(0)
minimal	1	0	0	0	0	0	1	1	1	0	1	0	1	0
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(1)	(1)	(3)	(2)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	1	1	3	2	0	0	1	0	0	1	0	0	0	0
Mineralization; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Mineralization; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Cyst; tubular; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Inflammation, Chronic; interstitial; focal	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(1)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	1	1	0	0	0	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cast; hyaline; tubule; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	1	0	1	0	0	0	0	0
KIDNEY, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
KIDNEY, RIGHT; (continued)														
mild	3	4	6	4	4	1	2	3	6	6	3	6	8	6
moderate	7	6	4	6	6	9	8	7	4	4	7	4	2	4
Basophilia; tubule; focal	(0)	(0)	(0)	(1)	(1)	(2)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	1	1	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	1	2	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(2)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	2	0	1	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation; purulent; pelvis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Mineralization; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Mineralization; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Dilation; tubule; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration, Neutrophilic; subcapsular; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
LACRIMAL GLAND, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
LACRIMAL GLAND, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	9	10	10	10	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	1	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LIVER;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
mild	3	5	3	4	3	4	2	4	7	8	6	4	8	9
moderate	7	4	7	6	7	6	8	5	3	2	4	6	2	1
Hematopoiesis; extramedullary; focal	(0)	(0)	(0)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	2	0	1	0	0	0	0	0	0	0	0
Hematopoiesis; extramedullary; multifocal	(2)	(4)	(2)	(1)	(1)	(0)	(2)	(3)	(3)	(1)	(7)	(5)	(6)	(5)
minimal	2	4	2	1	1	0	2	3	3	1	7	5	6	5
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	1	0	0	0
Infiltration; mixed; multifocal	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis; focal	(1)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	1	0	0	1	0	0	0	0	0	0	0	0	0	0
Necrosis; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Infiltration, Neutrophilic; focal	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	1	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(5)	(0)	(5)	(3)	(2)	(0)	(2)	(7)	(1)	(3)	(4)	(0)	(1)	(2)
minimal	5	0	5	3	2	0	2	7	1	3	4	0	1	2
Vacuolation; hepatocellular; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Vacuolation; hepatocellular; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Vacuolation; hepatocellular; periportal	(0)	(1)	(1)	(0)	(8)	(1)	(9)	(0)	(10)	(6)	(10)	(10)	(10)	(10)
minimal	0	1	1	0	5	1	5	0	4	5	2	1	6	2
mild	0	0	0	0	3	0	4	0	6	1	8	9	4	8
Infiltration, Eosinophilic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LIVER; (continued)														
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Pigmentation; brown; kupffer cell	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
LUNGS WITH BRONCHI;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	2	3	3	2	3	4	5	8	7	5	3	3	5	2
Ossification; focal	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)
minimal	0	1	0	1	0	0	0	0	1	0	0	1	0	0
Hemorrhage; acute; focal	(1)	(0)	(4)	(0)	(2)	(1)	(2)	(0)	(0)	(2)	(1)	(1)	(1)	(0)
minimal	1	0	1	0	2	0	0	0	0	1	1	0	0	0
mild	0	0	3	0	0	1	2	0	0	1	0	1	1	0
Hemorrhage; acute; multifocal	(3)	(2)	(1)	(3)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	1	1	3	0	0	0	0	0	0	0	0	0	0
mild	2	1	0	0	0	0	1	0	0	0	0	0	0	0
Hyperplasia; bronchial-associated lymphoid tissue	(4)	(6)	(3)	(6)	(4)	(3)	(2)	(1)	(2)	(4)	(4)	(3)	(5)	(4)
minimal	4	6	3	6	4	3	2	1	2	3	4	3	5	4
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Infiltration, Eosinophilic; perivascular ; focal	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	1	0	0	0	0	0	0	0	0
Infiltration, Eosinophilic; perivascular ; multifocal	(2)	(0)	(0)	(2)	(3)	(0)	(1)	(1)	(0)	(1)	(4)	(2)	(0)	(6)
minimal	2	0	0	1	3	0	1	1	0	1	2	1	0	6
mild	0	0	0	1	0	0	0	0	0	0	2	1	0	0
Infiltration; foamy; macrophage; alveolus ; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Pigmentation; brown; macrophage; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LUNGS WITH BRONCHI; (continued)														
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
LYMPH NODE, CERVICAL;														
Examined	(8)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Histocytosis	(8)	(10)	(9)	(10)	(10)	(9)	(8)	(9)	(9)	(10)	(10)	(10)	(8)	(9)
minimal	8	7	7	8	5	6	4	8	6	6	10	4	3	3
mild	0	3	2	2	5	3	4	1	3	4	0	6	5	6
Erythrophagocytosis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Pigmentation; brown; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	2	1	0
Hemorrhage	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Plasmacytosis	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Increased Cellularity; germinal center	(8)	(10)	(10)	(9)	(10)	(10)	(9)	(8)	(10)	(10)	(9)	(10)	(10)	(8)
minimal	5	3	3	8	2	2	1	3	1	0	7	2	1	0
mild	3	7	7	1	8	8	5	4	9	10	2	8	8	8
moderate	0	0	0	0	0	0	3	1	0	0	0	0	1	0
LYMPH NODE, ILIAC;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Histocytosis	(10)	(9)	(10)	(9)	(10)	(10)	(9)	(9)	(9)	(6)	(7)	(9)	(10)	(9)
minimal	3	5	6	3	3	3	2	1	7	2	5	0	2	4
mild	7	4	4	6	7	7	7	8	2	4	2	9	8	5
Plasmacytosis	(0)	(5)	(7)	(9)	(8)	(6)	(10)	(0)	(3)	(7)	(8)	(9)	(7)	(10)
minimal	0	2	1	0	1	4	0	0	2	1	0	0	1	0
mild	0	3	6	2	4	1	9	0	1	6	1	4	6	2
moderate	0	0	0	7	2	1	1	0	0	0	7	5	0	8
marked	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, ILIAC; (continued)														
Infiltration, Eosinophilic	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	1	0	0	0	1	0	0	0	0	0	0	1	0	0
Hemorrhage; acute	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Inflammation	(0)	(5)	(0)	(0)	(5)	(4)	(9)	(0)	(6)	(3)	(0)	(7)	(7)	(6)
minimal	0	4	0	0	0	1	1	0	1	1	0	2	2	1
mild	0	1	0	0	3	1	7	0	5	2	0	3	3	5
moderate	0	0	0	0	2	2	1	0	0	0	0	2	2	0
Increased Cellularity; germinal center	(8)	(9)	(9)	(10)	(10)	(10)	(10)	(3)	(8)	(10)	(8)	(9)	(10)	(10)
minimal	4	3	0	1	1	0	0	3	1	1	2	0	0	0
mild	4	5	6	9	7	8	8	0	6	7	4	6	10	6
moderate	0	1	3	0	2	2	2	0	1	2	2	3	0	4
LYMPH NODE, MESENTERIC;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Erythrophagocytosis	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Histocytosis	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)
minimal	5	0	1	0	1	0	0	0	2	0	0	1	0	0
mild	5	10	9	8	9	9	9	9	6	10	10	9	9	9
moderate	0	0	0	2	0	1	1	0	2	0	0	0	1	1
Infiltration, Eosinophilic	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	1	0	0
Increased Cellularity; germinal center	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(9)	(10)
minimal	1	0	0	1	0	1	1	0	1	0	1	0	0	0
mild	8	10	10	9	10	9	9	9	9	10	9	10	9	10
LYMPH NODE, RENAL;														
Examined	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Histocytosis	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
LYMPH NODE, RENAL; (continued)														
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Plasmacytosis	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Increased Cellularity; germinal center	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
MAMMARY GLANDS;														
Examined	(9)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	9	8	6	10	10	10	7	10	9	7	10
Not Examined: NOT PRESENT	1	0	0	1	0	0	0	0	0	0	0	0	0	0
Inflammation; mixed; interstitium	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation; mixed; interstitium; focal	(0)	(0)	(0)	(0)	(2)	(3)	(0)	(0)	(0)	(2)	(0)	(0)	(3)	(0)
mild	0	0	0	0	1	2	0	0	0	2	0	0	1	0
moderate	0	0	0	0	1	1	0	0	0	0	0	0	2	0
Inflammation; mixed; interstitium; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Inflammation; mixed; interstitium; lymphatic; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0
SKELETAL MUSCLE;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	9	10	5	9	9	10	10	7	10	10
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(2)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	1	0	0	2	0	0
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(4)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	4	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SKELETAL MUSCLE; (continued)														
Necrosis; myofiber; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	1	0	0
Necrosis; myofiber; multifocal	(0)	(0)	(0)	(0)	(1)	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	2	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
NERVE, SCIATIC;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	7	10	9	3	10	0	10	10	8	6	0	10	0
Inflammation; perineural	(0)	(3)	(0)	(1)	(7)	(0)	(10)	(0)	(0)	(1)	(4)	(10)	(0)	(10)
minimal	0	0	0	0	3	0	1	0	0	1	1	1	0	1
mild	0	0	0	0	2	0	2	0	0	0	3	2	0	3
moderate	0	2	0	1	2	0	5	0	0	0	0	7	0	5
marked	0	1	0	0	0	0	2	0	0	0	0	0	0	1
Vacuolation; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OPTIC NERVE, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	8	9	9	10	9	9
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Hemorrhage; acute; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(1)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	1	1
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OPTIC NERVE, RIGHT;														
Examined	(10)	(7)	(10)	(9)	(10)	(10)	(9)	(10)	(9)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	7	10	9	10	10	9	10	8	9	9	10	9	10
Not Examined: NOT PRESENT	0	3	0	1	0	0	1	0	1	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
OPTIC NERVE, RIGHT; (continued)														
Hemorrhage; acute; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Infiltration; foamy; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
OVARY, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	10	9	10
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	0	1	0
OVARY, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	10	10	10
OVIDUCT, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	9	10	10
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	1	0	0
OVIDUCT, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	10	10	10	10	10	10
PANCREAS;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	10	9	10	9	9	10	9	9	10	10	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Atrophy; acinar cell; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	1	0	0	0
Hyperplasia; acinar cell; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	1	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PARATHYROID, LEFT;														
Examined	(6)	(10)	(8)	(2)	(9)	(8)	(7)	(10)	(10)	(6)	(9)	(7)	(10)	(4)
Within Normal Limits	6	10	8	2	9	8	7	10	9	6	9	6	10	3
Not Examined: NOT PRESENT	4	0	2	8	1	2	3	0	0	4	1	3	0	6
Fibrosis; interstitial	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(1)
mild	0	0	0	0	0	0	0	0	1	0	0	1	0	1
PARATHYROID, RIGHT;														
Examined	(9)	(7)	(7)	(5)	(7)	(7)	(7)	(9)	(10)	(6)	(9)	(6)	(8)	(7)
Within Normal Limits	9	7	7	5	7	7	7	9	10	6	9	6	8	7
Not Examined: NOT PRESENT	1	3	3	5	3	3	3	1	0	4	1	4	2	3
PEYERS PATCHES;														
Examined	(8)	(6)	(9)	(9)	(10)	(10)	(9)	(10)	(6)	(8)	(8)	(8)	(7)	(9)
Within Normal Limits	1	1	0	0	1	0	0	0	0	1	0	0	0	0
Not Examined: NOT PRESENT	2	4	1	1	0	0	1	0	4	2	2	2	3	1
Mineralization; focal	(0)	(0)	(1)	(0)	(0)	(2)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(1)
minimal	0	0	1	0	0	2	1	0	0	0	0	0	1	1
Mineralization; multifocal	(0)	(1)	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
mild	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Inflammation, Granulomatous; follicular; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Increased Cellularity; germinal center	(7)	(5)	(9)	(9)	(9)	(10)	(9)	(10)	(6)	(7)	(8)	(8)	(7)	(9)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
mild	0	3	2	1	1	4	2	3	3	0	2	1	2	6
moderate	7	2	7	8	8	6	7	7	3	7	6	7	4	3
PITUITARY GLAND;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)
Within Normal Limits	10	9	10	10	10	10	7	10	9	10	10	10	9	9
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Cyst; pars distalis; few	(0)	(0)	(0)	(0)	(0)	(0)	(3)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	2	0	0	0	0	0	1	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
PITUITARY GLAND; (continued)														
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cyst; pars distalis; single	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	1	0	0	0	0	0
PROSTATE GLAND;														
Examined	(10)	(9)	(10)	(10)	(9)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	7	8	8	8	8	9	10	-	-	-	-	-	-	-
Not Examined: NO SECTION	0	1	0	0	1	0	0	-	-	-	-	-	-	-
Infiltration; mixed	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	1	0	0	0	0	0	-	-	-	-	-	-	-
Infiltration; mixed; focal	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	0	1	1	0	0	0	-	-	-	-	-	-	-
Inflammation; purulent; focal	(1)	(0)	(0)	(1)	(0)	(1)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	1	0	0	1	0	1	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	1	0	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	2	0	1	0	0	0	0	-	-	-	-	-	-	-
SALIVARY GLANDS, MANDIBULAR;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
SALIVARY GLANDS, SUBLINGUAL;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)	(9)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	9	10	10	9	10	10	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	1	0	0	1	0	0	0
SALIVARY GLANDS, PAROTIS;														
Examined	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	10	9	9	10	10	10	10	10	10	10	10	10	9	10
Not Examined: NOT PRESENT	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SEMINAL VESICLES;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	10	10	10	10	9	10	10	-	-	-	-	-	-	-
Infiltration; mixed; surrounding tissue; fat; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
moderate	0	0	0	0	1	0	0	-	-	-	-	-	-	-
SKIN;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	9	10	9	10	10	10	10	7	10	4
Infiltration; mixed; dermis; subcutis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(2)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	1
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; mixed; dermis; subcutis; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(4)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	1
moderate	0	0	0	0	0	0	0	0	0	0	0	0	0	2
Infiltration; mixed; subcutaneous; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Necrosis; muscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Infiltration, Neutrophilic; muscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
SPINAL CORD;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	9
Cyst; keratinized; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
SPLEEN;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
SPLEEN; (continued)														
Within Normal Limits	1	0	5	1	2	5	5	0	1	6	1	3	3	0
Congestion	(9)	(10)	(4)	(9)	(6)	(5)	(4)	(10)	(9)	(3)	(9)	(4)	(7)	(7)
minimal	9	9	4	9	6	4	4	7	6	2	8	4	6	7
mild	0	1	0	0	0	1	0	3	3	1	1	0	1	0
Hematopoiesis; increased	(0)	(0)	(3)	(0)	(2)	(0)	(2)	(0)	(0)	(2)	(0)	(7)	(0)	(8)
minimal	0	0	3	0	0	0	2	0	0	2	0	4	0	6
mild	0	0	0	0	2	0	0	0	0	0	0	3	0	2
STOMACH, GLANDULAR;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	1	0	5	0	0	4	0	0	3	5	0	0	6	1
Infiltration, Eosinophilic	(9)	(9)	(4)	(10)	(10)	(5)	(9)	(10)	(5)	(4)	(10)	(10)	(3)	(8)
minimal	4	9	4	2	7	5	9	7	5	4	4	6	3	6
mild	4	0	0	8	3	0	0	3	0	0	6	4	0	2
moderate	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Dilation; glandular; focal	(0)	(0)	(1)	(0)	(0)	(1)	(1)	(0)	(0)	(1)	(1)	(0)	(1)	(0)
minimal	0	0	1	0	0	1	0	0	0	1	1	0	1	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Dilation; glandular; multifocal	(0)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(1)
minimal	0	2	0	1	0	0	0	0	1	1	0	0	0	1
Cyst; single	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia; chief cell	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Hyperplasia; chief cell; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(0)	(1)	(0)	(0)	(1)	(1)	(0)	(1)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	1	0	0	1	0	0	1	0	0	1	0	0
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
STOMACH, GLANDULAR; (continued)														
Infiltration, Neutrophilic; mucosa; focal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	0	0	0	0	0
STOMACH, NONGLANDULAR;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	10	10	10	10	10	10	10	10	10	10	10	10	10	10
TESTIS, LEFT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	10	10	10	10	10	10	10	-	-	-	-	-	-	-
TESTIS, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	10	10	10	10	10	10	10	-	-	-	-	-	-	-
THYMUS;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	7	3	4	5	6	5	5	3	2	8	6	5	5	2
Cyst; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Hemorrhage; acute; focal	(2)	(2)	(2)	(2)	(0)	(1)	(1)	(1)	(3)	(0)	(0)	(3)	(1)	(2)
minimal	2	1	2	1	0	1	0	1	2	0	0	3	1	2
mild	0	1	0	1	0	0	1	0	1	0	0	0	0	0
Hemorrhage; acute; multifocal	(1)	(5)	(4)	(3)	(4)	(4)	(4)	(6)	(5)	(2)	(4)	(2)	(3)	(6)
minimal	1	4	4	3	2	3	3	5	3	2	3	2	2	6
mild	0	1	0	0	2	1	1	1	2	0	1	0	1	0
THYROID, LEFT;														
Examined	(10)	(10)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	9	10	10	10	9	7	9	10	9	10	10
Not Examined: NOT PRESENT	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Cyst; keratinized; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(3)	(1)	(0)	(1)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
THYROID, LEFT; (continued)														
minimal	1	0	0	0	0	0	0	1	3	1	0	1	0	0
THYROID, RIGHT;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)
Within Normal Limits	9	8	10	10	10	9	10	10	10	10	10	10	8	10
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Cyst; keratinized; multiple	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Cyst; keratinized; single	(1)	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	1	1	0	0	0	1	0	0	0	0	0	0	1	0
TONGUE;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	9	10	10	10	10	10	10	9	10	10	9	10	10	10
Hemorrhage; acute; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	1	0	0	0	0	0	0
TRACHEA;														
Examined	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	5	10	7	8	8	10	10	8	9	9	7	9	9	10
Infiltration; lymphohistiocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration; lymphohistiocytic; multifocal	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration; mixed	(1)	(0)	(2)	(2)	(2)	(0)	(0)	(2)	(0)	(1)	(3)	(1)	(0)	(0)
minimal	1	0	2	2	2	0	0	2	0	1	3	1	0	0
Pigmentation; brown; macrophage; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Infiltration, Lymphocytic; multifocal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Main Study Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Number of Animals Completed:	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
TRACHEA; (continued)														
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
URINARY BLADDER;														
Examined	(10)	(9)	(10)	(9)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(9)	(10)	(10)
Within Normal Limits	10	9	9	8	10	10	10	9	10	10	10	8	10	9
Not Examined: INSUFFICIENT TISSUE TO EVALUATE	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Not Examined: NOT PRESENT	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)	(1)
minimal	0	0	1	1	0	0	0	1	0	0	0	1	0	1
UTERUS;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	10	7	6	8	10	10	9
Dilation	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(3)	(4)	(2)	(0)	(0)	(1)
mild	-	-	-	-	-	-	-	0	3	4	2	0	0	1
VAGINA;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Within Normal Limits	-	-	-	-	-	-	-	7	5	5	9	8	6	7
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(3)	(5)	(5)	(1)	(2)	(4)	(3)
minimal	-	-	-	-	-	-	-	1	1	2	0	2	1	1
mild	-	-	-	-	-	-	-	2	4	3	1	0	3	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
ADRENAL GLAND, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	2	4	2	3	4	3	2	4	2	3	5	4	4
Dilation; vascular	(1)	(3)	(1)	(3)	(2)	(1)	(2)	(3)	(1)	(3)	(2)	(0)	(1)	(1)
minimal	1	3	1	3	2	1	2	3	1	3	2	0	1	1
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
ADRENAL GLAND, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	3	5	5	4	3	3	4	4	5	3	5	5	4
Dilation; vascular	(1)	(2)	(0)	(0)	(1)	(2)	(2)	(1)	(1)	(0)	(2)	(0)	(0)	(1)
minimal	1	2	0	0	1	2	2	1	1	0	2	0	0	1
AORTA ABDOMINALIS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BONE, OS FEMORIS WITH JOINT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	4	5	5	5	5	5	5	4	5	5
Infiltration, Lymphocytic; surrounding tissue; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Infiltration; lymphohistiocytic; surrounding tissue; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
BONE MARROW, OS FEMORIS WITH JOINT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BONE, STERNUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
BRAIN, BRAIN STEM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BRAIN, CEREBELLUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
BRAIN, CEREBRUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CERVIX;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	4	2	3	1	2	3	3
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(1)	(3)	(2)	(4)	(3)	(2)	(2)
minimal	-	-	-	-	-	-	-	0	1	1	1	0	0	1
mild	-	-	-	-	-	-	-	1	2	1	3	3	2	1
Cyst; keratinized	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
moderate	-	-	-	-	-	-	-	0	0	0	0	0	1	0
EPIDIDYMIS, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	1	0	1	1	2	1	3	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	1	0	1	0	0	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(4)	(4)	(4)	(3)	(3)	(4)	(2)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	4	4	3	3	3	4	2	-	-	-	-	-	-	-
mild	0	0	1	0	0	0	0	-	-	-	-	-	-	-
EPIDIDYMIS, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	2	1	0	1	2	0	2	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(3)	(4)	(5)	(4)	(3)	(5)	(3)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	3	4	5	4	3	5	3	-	-	-	-	-	-	-

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
EPIDIDYMIS, RIGHT; (continued)														
Oligospermia	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	0	0	1	0	0	0	-	-	-	-	-	-	-
ESOPHAGUS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
EYE, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
EYE, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
HARDERIAN GLAND, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	4	5	5	5	5	5	5	4	4	5	4
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Infiltration, Lymphocytic; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation, Chronic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
HARDERIAN GLAND, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	5	5	5	5	5	4	4	4	5	5	4	4
Infiltration, Lymphocytic; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	1	1	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(1)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
HARDERIAN GLAND, RIGHT; (continued)														
minimal	0	0	0	0	0	0	0	0	0	1	0	0	1	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Inflammation, Chronic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0
HEART;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	3	4	4	5	5	3	5	5	5	5	4	5	5
Infiltration; lymphohistiocytic; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(1)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	1	1	0	0	1	0	0	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	1	0	0	0	0	0	0	0
INJECTION SITE I;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	0	0	0	0	4	0	5	0	0	0	0	1	1
Fibrosis; intramuscular / interstitial	(0)	(1)	(0)	(2)	(1)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	1	0	2	1	0	0	0	0	0	1	0	0	0
Fibrosis; intramuscular / interstitial; multifocal	(0)	(0)	(3)	(2)	(3)	(0)	(4)	(0)	(3)	(1)	(3)	(1)	(0)	(4)
minimal	0	0	3	2	3	0	4	0	3	1	3	1	0	4
Fibrosis; inter- / perimuscular	(0)	(5)	(5)	(5)	(5)	(1)	(5)	(0)	(5)	(5)	(5)	(4)	(4)	(4)
minimal	0	1	1	0	2	1	1	0	1	4	1	4	4	0
mild	0	4	4	5	3	0	4	0	4	1	4	0	0	4
Fibrosis; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation; lymphohistiocytic; intramuscular / interstitial; multifocal	(0)	(2)	(2)	(5)	(4)	(0)	(3)	(0)	(4)	(1)	(4)	(1)	(0)	(4)
minimal	0	2	2	5	3	0	1	0	4	1	2	0	0	2
mild	0	0	0	0	1	0	2	0	0	0	2	1	0	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INJECTION SITE I; (continued)														
Inflammation; lymphohistiocytic; inter- / perimuscular	(0)	(3)	(2)	(4)	(3)	(0)	(3)	(0)	(4)	(1)	(5)	(0)	(1)	(4)
minimal	0	1	2	1	2	0	0	0	2	1	1	0	1	0
mild	0	2	0	3	1	0	3	0	2	0	4	0	0	4
Inflammation; lymphohistiocytic; inter- / perimuscular; multifocal	(0)	(2)	(2)	(1)	(2)	(1)	(2)	(0)	(0)	(2)	(0)	(4)	(2)	(0)
minimal	0	2	2	0	1	1	1	0	0	2	0	2	2	0
mild	0	0	0	1	1	0	1	0	0	0	0	2	0	0
Mineralization; inter- / perimuscular; multifocal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Multinucleated Macrophages; inter- / perimuscular; multifocal	(0)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	2	0	0	0	0	0	0	0	0	0	0	0	0
INJECTION SITE II;														
Examined	(5)	(1)	(0)	(0)	(5)	(0)	(5)	(5)	(1)	(0)	(0)	(5)	(0)	(5)
Within Normal Limits	5	1	0	0	0	0	0	5	0	0	0	1	0	1
Fibrosis; inter- / perimuscular	(0)	(0)	(0)	(0)	(5)	(0)	(5)	(0)	(1)	(0)	(0)	(3)	(0)	(4)
minimal	0	0	0	0	2	0	2	0	1	0	0	2	0	3
mild	0	0	0	0	3	0	3	0	0	0	0	1	0	1
Fibrosis; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Fibrosis; intramuscular / interstitial	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Fibrosis; intramuscular / interstitial; multifocal	(0)	(0)	(0)	(0)	(3)	(0)	(4)	(0)	(0)	(0)	(0)	(1)	(0)	(2)
minimal	0	0	0	0	2	0	4	0	0	0	0	1	0	2
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Fibrosis; dermis; subcutis; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	0	1	0	0	0	0	0

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INJECTION SITE II; (continued)														
Inflammation; lymphohistiocytic; inter- / perimuscular	(0)	(0)	(0)	(0)	(3)	(0)	(4)	(0)	(0)	(0)	(0)	(1)	(0)	(4)
minimal	0	0	0	0	2	0	2	0	0	0	0	0	0	1
mild	0	0	0	0	1	0	2	0	0	0	0	1	0	3
Inflammation; lymphohistiocytic; inter- / perimuscular; multifocal	(0)	(0)	(0)	(0)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(2)	(0)	(0)
minimal	0	0	0	0	1	0	1	0	0	0	0	1	0	0
mild	0	0	0	0	1	0	0	0	0	0	0	0	0	0
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Inflammation; lymphohistiocytic; intramuscular / interstitial; multifocal	(0)	(0)	(0)	(0)	(5)	(0)	(4)	(0)	(0)	(0)	(0)	(2)	(0)	(3)
minimal	0	0	0	0	3	0	2	0	0	0	0	0	0	0
mild	0	0	0	0	2	0	2	0	0	0	0	2	0	3
INTESTINE, CECUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	4	5	5	5	5	5	5	4	4	4	5	5	5
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0
mild	1	1	0	0	0	0	0	0	0	1	0	0	0	0
moderate	0	0	0	0	0	0	0	0	1	0	0	0	0	0
INTESTINE, COLON;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	1	5	3	5	5	5	5	4	5	5	4	4
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(1)	(4)	(0)	(2)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)
mild	0	1	3	0	2	0	0	0	0	1	0	0	1	0
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
INTESTINE, DUODENUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
INTESTINE, ILEUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
INTESTINE, JEJUNUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
INTESTINE, RECTUM;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	3	3	5	3	4	3	3	4	5	4	5	5	3
Infiltration, Eosinophilic; increased	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	1	0	0	1	0	0	0	0	0	1
Hyperplasia; mucosa-associated lymphoid tissue	(1)	(2)	(2)	(0)	(2)	(1)	(2)	(0)	(1)	(0)	(1)	(0)	(0)	(1)
minimal	0	1	0	0	0	0	1	0	1	0	0	0	0	0
mild	1	1	1	0	2	1	1	0	0	0	1	0	0	1
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Nematodiasis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
KIDNEY, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Congestion	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)
mild	1	0	0	0	0	0	0	1	0	0	0	1	0	1
moderate	4	5	5	5	5	5	5	4	5	5	4	4	5	4
Basophilia; tubule; focal	(1)	(0)	(1)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	1	0	1	0	0	0	0	0	0
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(1)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
KIDNEY, LEFT; (continued)														
minimal	0	0	0	0	0	0	1	0	1	0	0	1	0	0
Infiltration, Lymphocytic; multifocal	(2)	(0)	(1)	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	2	0	1	1	1	0	0	0	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Cast; hyaline; tubule; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Degeneration; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
KIDNEY, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	(4)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
mild	1	0	1	0	0	0	0	1	1	0	0	1	0	2
moderate	3	5	4	5	5	5	5	4	4	5	5	4	5	3
Basophilia; tubule; focal	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	2	0	0	0	1	0	0	0
Basophilia; tubule; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	1	1	0
Infiltration, Lymphocytic; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	1	0	0	0	0	0	0	0
Cast; hyaline; tubule; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(1)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	1	0	0	1	0	1	1	0	0	0
Mineralization; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Pyelonephritis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Inflammation, Chronic; interstitial; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
moderate	0	0	1	0	0	0	0	0	0	0	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LACRIMAL GLAND, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
LACRIMAL GLAND, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
LIVER;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Congestion	(5)	(5)	(4)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
mild	2	1	0	0	0	1	0	1	2	3	0	1	1	3
moderate	3	4	4	5	5	3	5	4	3	2	5	4	4	2
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration; mixed; multifocal	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	1	0	0	0	0	0	0	0	0
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Necrosis; focal	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	0
marked	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Infiltration, Lymphocytic; multifocal	(4)	(5)	(5)	(4)	(4)	(2)	(2)	(2)	(3)	(4)	(2)	(2)	(4)	(0)
minimal	4	5	5	4	4	2	2	2	3	4	2	2	4	0
Vacuolation; hepatocellular; multifocal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Vacuolation; hepatocellular; periportal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	1	0
LUNGS WITH BRONCHI;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	1	1	3	1	2	1	2	3	1	4	2	3	5	2
Ossification; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Hemorrhage; acute; focal	(0)	(1)	(0)	(0)	(0)	(1)	(0)	(1)	(1)	(0)	(0)	(0)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LUNGS WITH BRONCHI; (continued)														
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
mild	0	0	0	0	0	1	0	0	1	0	0	0	0	0
moderate	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage; acute; multifocal	(0)	(0)	(0)	(2)	(1)	(2)	(2)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	2	0	0	0	0	0	0	0
mild	0	0	0	2	1	2	0	0	1	0	0	0	0	0
Hyperplasia; bronchial-associated lymphoid tissue	(3)	(3)	(2)	(3)	(2)	(3)	(1)	(1)	(2)	(0)	(3)	(1)	(0)	(1)
minimal	3	3	2	2	2	3	1	1	2	0	3	1	0	1
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration, Eosinophilic; perivascular ; multifocal	(1)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(2)
minimal	1	1	0	0	0	0	0	0	0	1	0	0	0	2
Infiltration; macrophage; alveolus; focal	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	1	0	0	0	0	0	0	0	0	0	0
Infiltration; mixed; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Infiltration; mixed; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Pigmentation; brown; macrophage; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
LYMPH NODE, CERVICAL;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Histocytosis	(5)	(5)	(5)	(3)	(5)	(5)	(5)	(5)	(4)	(5)	(4)	(5)	(5)	(4)
minimal	5	5	4	1	4	3	3	5	1	1	3	2	5	3
mild	0	0	1	2	1	2	2	0	3	4	1	3	0	1
Pigmentation; brown; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Increased Cellularity; germinal center	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
minimal	0	1	0	0	2	2	0	2	0	0	0	0	1	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, CERVICAL; (continued)														
mild	4	3	5	5	3	3	5	3	5	4	4	5	4	4
moderate	1	1	0	0	0	0	0	0	0	1	1	0	0	0
LYMPH NODE, ILIAC;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Histocytosis	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(3)	(5)	(5)	(4)
minimal	3	2	2	3	1	2	4	5	4	4	2	1	3	3
mild	2	3	3	2	3	2	1	0	1	1	1	4	2	1
moderate	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Plasmacytosis	(0)	(0)	(0)	(2)	(3)	(0)	(1)	(0)	(3)	(3)	(3)	(5)	(1)	(4)
minimal	0	0	0	2	2	0	1	0	2	2	3	2	1	1
mild	0	0	0	0	1	0	0	0	1	1	0	3	0	3
Infiltration; macrophage; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Infiltration; macrophage; multifocal	(0)	(0)	(1)	(1)	(5)	(3)	(5)	(0)	(3)	(0)	(3)	(5)	(4)	(4)
minimal	0	0	1	1	0	2	4	0	3	0	2	2	4	0
mild	0	0	0	0	5	1	1	0	0	0	1	2	0	3
moderate	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Increased Cellularity; germinal center	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(4)	(4)
minimal	1	3	1	3	1	4	1	2	2	1	1	0	3	0
mild	4	1	4	1	4	1	4	2	3	3	4	3	1	3
moderate	0	1	0	1	0	0	0	0	0	1	0	2	0	1
LYMPH NODE, MESENTERIC;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Erythrophagocytosis	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Histocytosis	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)
minimal	3	2	1	1	0	3	0	2	0	1	0	0	1	1
mild	2	3	4	4	5	2	5	2	5	4	5	5	4	4
Pigmentation; macrophage	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
LYMPH NODE, MESENTERIC; (continued)														
mild	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Increased Cellularity; germinal center	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(3)
minimal	0	0	0	0	0	2	0	0	0	0	0	1	1	0
mild	5	5	5	5	5	2	5	5	5	5	5	3	4	3
moderate	0	0	0	0	0	1	0	0	0	0	0	0	0	0
MAMMARY GLANDS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SKELETAL MUSCLE;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	4	5	5	5	4
Infiltration; lymphohistiocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	0	1
NERVE, SCIATIC;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)
Within Normal Limits	5	5	5	5	5	5	3	5	5	5	5	4	4	4
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Inflammation; perineural	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(0)	(0)	(1)	(0)	(1)
minimal	0	0	0	0	0	0	2	0	0	0	0	0	0	1
mild	0	0	0	0	0	0	0	0	0	0	0	1	0	0
OPTIC NERVE, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	5	5	5	5	5	4	5	4	5	5	5	5
Not Examined: INSUFFICIENT TISSUE TO EVALUATE	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Pigmentation; brown; macrophage; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	1	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
OPTIC NERVE, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	4	4	5	5	5	5	5	5	5	5	5	5
Pigmentation; brown; macrophage; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage; acute; focal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Infiltration; foamy; macrophage	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	0	0	1	0	0	0	0	0	0	0	0	0	0
OVARY, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	5	5	5
OVARY, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	5	5	5
OVIDUCT, LEFT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	5	5	5
OVIDUCT, RIGHT;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(4)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	5	5	4	5	5
Not Examined: NOT PRESENT	-	-	-	-	-	-	-	0	0	0	0	1	0	0
PANCREAS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	4	5	5	5
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	1	0	0	0
PARATHYROID, LEFT;														
Examined	(2)	(2)	(3)	(5)	(5)	(4)	(4)	(4)	(5)	(1)	(4)	(3)	(4)	(5)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PARATHYROID, LEFT; (continued)														
Within Normal Limits	2	2	3	5	5	4	4	4	5	1	4	3	4	5
Not Examined: NOT PRESENT	3	3	2	0	0	1	1	1	0	4	1	2	1	0
PARATHYROID, RIGHT;														
Examined	(4)	(3)	(4)	(3)	(4)	(5)	(5)	(3)	(5)	(4)	(4)	(2)	(4)	(4)
Within Normal Limits	4	3	4	3	4	5	5	3	5	4	4	2	4	4
Not Examined: NO SECTION	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Not Examined: NOT PRESENT	1	2	1	2	1	0	0	1	0	1	1	3	1	1
PEYERS PATCHES;														
Examined	(4)	(3)	(4)	(5)	(5)	(4)	(3)	(5)	(5)	(5)	(5)	(4)	(4)	(5)
Within Normal Limits	0	0	0	0	0	1	0	0	0	0	2	0	0	1
Not Examined: NOT PRESENT	1	2	1	0	0	1	2	0	0	0	0	1	1	0
Mineralization; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Mineralization; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
mild	0	0	0	0	0	0	0	0	0	1	0	1	0	0
Inflammation, Granulomatous; follicular; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)
mild	1	0	0	0	0	0	0	0	0	0	1	0	0	0
Inflammation, Granulomatous; follicular; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	1	0	0
mild	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Increased Cellularity; germinal center	(4)	(3)	(4)	(5)	(5)	(3)	(3)	(5)	(5)	(5)	(3)	(4)	(4)	(4)
mild	0	2	1	1	0	1	1	2	0	1	0	0	0	0
moderate	4	1	3	4	5	2	2	3	5	4	3	4	4	4
PITUITARY GLAND;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	4	4	5	5	5	5	5	5	5	4	5	5	5	5
Cyst; pars distalis; few	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
mild	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Cyst; pars intermedia	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
PITUITARY GLAND; (continued)														
minimal	1	0	0	0	0	0	0	0	0	1	0	0	0	0
PROSTATE GLAND;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	5	4	2	1	4	2	3	-	-	-	-	-	-	-
Inflammation; purulent; focal	(0)	(0)	(0)	(0)	(1)	(1)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	0	0	1	1	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; widespread	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	0	0	0	1	0	0	0	-	-	-	-	-	-	-
Infiltration, Lymphocytic; focal	(0)	(1)	(2)	(1)	(0)	(0)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	1	1	0	0	0	-	-	-	-	-	-	-
mild	0	1	0	0	0	0	0	-	-	-	-	-	-	-
moderate	0	0	1	0	0	0	1	-	-	-	-	-	-	-
Infiltration, Lymphocytic; multifocal	(0)	(0)	(1)	(2)	(0)	(2)	(1)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	0	1	1	0	2	0	-	-	-	-	-	-	-
mild	0	0	0	1	0	0	1	-	-	-	-	-	-	-
SALIVARY GLANDS, MANDIBULAR;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SALIVARY GLANDS, SUBLINGUAL;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	4
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	0	0	0	0	1
SALIVARY GLANDS, PAROTIS;														
Examined	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	4	5	5	5	5	5	5	5	5	5
Not Examined: NOT PRESENT	0	0	0	0	1	0	0	0	0	0	0	0	0	0
SEMINAL VESICLES;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	5	4	5	5	5	5	5	-	-	-	-	-	-	-

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
SEMINAL VESICLES; (continued)														
Infiltration, Lymphocytic; focal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	0	1	0	0	0	0	0	-	-	-	-	-	-	-
SKIN;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SPINAL CORD;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
SPLEEN;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	2	1	3	3	3	3	3	3	2	1	2	3	0	2
Congestion	(3)	(4)	(2)	(2)	(2)	(2)	(2)	(2)	(3)	(4)	(3)	(2)	(5)	(3)
minimal	1	3	1	2	2	2	2	2	2	2	2	2	4	3
mild	2	1	1	0	0	0	0	0	1	2	1	0	1	0
STOMACH, GLANDULAR;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	0	0	0	2	1	1	0	1	0	1	0	0	1	2
Infiltration, Eosinophilic	(5)	(5)	(5)	(3)	(4)	(4)	(5)	(4)	(5)	(4)	(5)	(5)	(4)	(3)
minimal	4	3	2	2	3	3	5	4	5	4	5	5	4	1
mild	1	2	3	1	1	1	0	0	0	0	0	0	0	2
Dilation; glandular; focal	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)
minimal	0	0	0	0	1	0	0	0	0	0	0	1	0	0
Dilation; glandular; multifocal	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	1
Cyst; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	1	0	0	0	0
Hyperplasia; mucosa-associated lymphoid tissue	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
mild	0	0	0	0	0	0	1	0	0	1	0	0	0	0

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
STOMACH, NONGLANDULAR;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	5	5	5	5	5	5
TESTIS, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	3	5	5	4	5	5	5	-	-	-	-	-	-	-
Spermatid Giant Cells; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	1	0	0	0	0	0	0	-	-	-	-	-	-	-
Dilation; tubular	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
mild	1	0	0	1	0	0	0	-	-	-	-	-	-	-
TESTIS, RIGHT;														
Examined	(5)	(4)	(5)	(5)	(5)	(5)	(5)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Within Normal Limits	4	4	5	4	5	5	5	-	-	-	-	-	-	-
Not Examined: NOT PRESENT	0	1	0	0	0	0	0	-	-	-	-	-	-	-
Dilation; tubular	(1)	(0)	(0)	(1)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
moderate	1	0	0	1	0	0	0	-	-	-	-	-	-	-
Infiltration; lymphoplasmacytic; focal	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
moderate	1	0	0	0	0	0	0	-	-	-	-	-	-	-
Spermatocoele; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
minimal	1	0	0	0	0	0	0	-	-	-	-	-	-	-
THYMUS;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	3	4	3	4	3	2	3	4	3	4	3	5	3	4
Hemorrhage; acute; focal	(1)	(0)	(0)	(0)	(0)	(2)	(0)	(0)	(1)	(0)	(0)	(0)	(1)	(0)
minimal	1	0	0	0	0	2	0	0	1	0	0	0	1	0
Hemorrhage; acute; multifocal	(1)	(1)	(2)	(1)	(2)	(1)	(2)	(1)	(1)	(1)	(2)	(0)	(1)	(1)
minimal	1	0	1	1	2	1	2	0	1	1	2	0	0	1
mild	0	1	1	0	0	0	0	1	0	0	0	0	1	0
THYROID, LEFT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(4)	(5)	(5)	(5)	(5)
Within Normal Limits	4	5	5	5	5	5	5	5	5	4	5	5	5	5

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
THYROID, LEFT; (continued)														
Not Examined: NOT PRESENT	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Cyst; keratinized; single	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	1	0	0	0	0	0	0	0	0	0	0	0	0	0
THYROID, RIGHT;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	5	4	5	5	5	4	5
Cyst; keratinized; multiple	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Cyst; keratinized; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
TONGUE;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	4	5	5	5	5	5	5	5	5	5	4	5
Granuloma; single	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)
minimal	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Granuloma; hair; single	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	1	0	0	0	0	0	0	0	0	0	0	0
TRACHEA;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	4	5	4	5	5	5	5	4	4	5	5	5	4
Infiltration; lymphohistiocytic; multifocal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)
minimal	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Infiltration, Lymphocytic; multifocal	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)
minimal	0	1	0	0	0	0	0	0	0	1	0	0	0	0
URINARY BLADDER;														
Examined	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	5	5	5	5	5	5	5	4	5	5	5	5	5	5

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Microscopic Findings by Severity

Observations: Neo-Plastic and Non Neo-Plastic	MALES							FEMALES						
Removal Reasons: Recovery Period Animals	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/	Group 1: Control	Group 2: 30 µg/	Group 3: 10 µg/	Group 4: 30 µg/	Group 5: 100 µg/	Group 6: 30 µg/	Group 7: 100 µg/
Number of Animals on Study :	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Number of Animals Completed:	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
URINARY BLADDER; (continued)														
Infiltration, Lymphocytic; focal	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)	(0)
minimal	0	0	0	0	0	0	0	1	0	0	0	0	0	0
UTERUS;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	5	5	4	5	4	5	5
Dilation	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(1)	(0)	(1)	(0)	(0)
mild	-	-	-	-	-	-	-	0	0	1	0	0	0	0
moderate	-	-	-	-	-	-	-	0	0	0	0	1	0	0
VAGINA;														
Examined	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Within Normal Limits	-	-	-	-	-	-	-	4	2	3	1	1	3	2
Keratinization; epithelial	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(1)	(3)	(2)	(4)	(4)	(2)	(3)
minimal	-	-	-	-	-	-	-	0	2	1	1	0	0	2
mild	-	-	-	-	-	-	-	1	1	1	3	4	2	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		+	N	N	N	N	N	N	N	N	N	N	N	N	+	N
Dilation; vascular		1	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	+	N	N	N	N	+	N	N
Dilation; vascular		.	.	.	.	.	.	.	1	.	.	.	.	1	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		+	+	+	N	+	+	+	N	N	+	N	+	+	+	+
Infiltration, Lymphocytic		1	1	1	.	1	1	1	.	.	1	.	1	1	1	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	N	N	+	+	N	+	+	+	N	N	+	+	+
Infiltration, Lymphocytic		1	1	.	.	1	1	.	1	1	1	.	.	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	+	N	N	+	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	1	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	N	N	N	N	+	+	+	+	+	N	N	N	N	N
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		1	.	.	.	.	1	1	1	1	1	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1	1	1
	NUMBER	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5			
INJECTION SITE I; (Continued)																			
Hyperplasia; epidermal																			
Scab; epidermal																			
myofiber; Necrosis																			
myofiber; Degeneration												1							
muscle; Regeneration												1							
dermis; subcutis; Necrosis																			
subcutis; Hemorrhage																			
subcutis; Inflammation; mixed																			
subcutis; Edema																			
intramuscular / interstitial; Fibrosis																			
intramuscular / interstitial; Inflammation; lymphohistiocytic																			
intramuscular / interstitial; Inflammation; mixed																			
intramuscular / interstitial; Edema																			
inter- / perimuscular; Fibrosis																			
inter- / perimuscular; Inflammation; lymphocytic																			
inter- / perimuscular; Inflammation; mixed																			
inter- / perimuscular; Inflammation; lymphohistiocytic																			
inter- / perimuscular; Mineralization																			
inter- / perimuscular; Edema																			
inter- / perimuscular; Multinucleated Macrophages																			
epidermis; Ulceration																			
perivascular; Inflammation; plasmacytic																			
INJECTION SITE II;		+	N	N	N	+	+	N	N	N	N	N	N	N					
Hyperplasia; epidermal																			
Scab; epidermal																			
Ulceration; epidermal																			

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		2	.	.	.	.	.	.	1	1	1	.	.	.	.	.
Inflammation; mixed		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	3	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	+	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	2	.	.	.	.	.	.	2	.	.	.	
KIDNEY, LEFT;		+	+	+	N	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	.	3	3	3	2	3	3	3	3	2	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	1	.	.	.	.	1	1
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	2	.	.	.	.	.	.	1
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	N	+	+	+	+	
Congestion		2	3	3	3	3	3	2	2	3	3	.	3	2	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	2	3	3	3	2	3	2	3	3	3	2
Hematopoiesis; extramedullary		.	.	.	.	.	1	.	.	1	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	2	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration, Lymphocytic		.	1	1	.	.	1	1	.	.	1	1	1	1	1	.
Vacuolation; hepatocellular		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	N	+	+	+	+	+	+	+	+	N	+	
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	1	.	.	2	1	.	.	2	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	.	.	.	.	1	1	1	.	1	1	1	.	.
perivascular; Infiltration, Eosinophilic		.	.	1	.	1	.	.	.	.	.	.	.	.	.	1
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	X	+	+	X	+	+	+	+	+	+	+
Histocytosis		1	1	1	1	.	1	1	.	1	1	1	1	1	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	1	.	1	1	.	1	2	2	3	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	1	1	2	2	2	2	2	1	1	2	1	1	2
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	1	1	2	1	.	2	.	1	2	2	2	1	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	1	2	1	2	1	1	1	2	1	1	1	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	1	2	.	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	X	N	X	X	N	X	N	N	N	X	N	X	N	X
PARATHYROID, RIGHT;		N	N	N	X	N	N	N	N	N	N	N	X	N	N	N
PEYERS PATCHES;		+	+	+	+	N	X	+	+	X	+	+	+	+	X	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	2	.	.	.
germinal center; Increased Cellularity		3	3	3	3	.	.	3	3	.	3	3	3	3	3	.	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	+	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
PROSTATE GLAND;		N	N	N	N	N	+	+	N	+	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	2	.	2	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	N	+	+	+	+	+	+	+	+	+	N	+	N	
Congestion		1	.	1	1	1	1	1	1	1	1	2	1	.	2	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	N	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	2	1	2	1	2	1	.	3	2	1	2	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
THYMUS;		+	N	N	N	+	N	N	N	+	N	+	N	N	N	+
Hemorrhage; acute		1	.	.	.	1	.	.	.	1	.	1	.	.	.	1
THYROID, LEFT;		N	N	N	N	N	N	N	+	N	N	N	+	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	1	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	+	+	+	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	1	.	.	1	.	1	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
	NUMBER	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	+	N	+	+	N
Dilation; vascular		.	.	.	.	.	.	.	.	1	.	1	.	1	1	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	+	N	N	N	N	N	N	+	+	N	N	N	
Dilation; vascular		.	.	1	.	.	.	.	.	.	1	1	.	.	.	
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
AORTA ABDOMINALIS;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		+	+	+	+	+	N	+	N	+	+	+	+	+	+	+
Infiltration, Lymphocytic		1	1	1	1	1	.	1	.	1	1	1	1	1	1	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	+	+	+	+	N	+	+	+	+	N	+	+	+
Infiltration, Lymphocytic		1	1	1	1	1	1	.	1	1	1	1	.	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		+	N	N	N	N	N	N	N	N	N	+	N	+	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	.	.	.	.	1	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	3	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		2	2	3	3	3	3	3	3	.	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	.	2	1	1	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	.	3	.	3	3	.	.	2	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	1	2	2	.	2	2	2	.	.	1	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	.	1	.	.
intramuscular / interstitial; Inflammation; mixed		3	2	3	.	3	2	1	2	2	3	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	1	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	2	3	2	3	3	2	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	1	1	1
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	1	2	.	.	.
inter- / perimuscular; Edema		3	2	3	.	3	3	.	.	2	4	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	2	2	.	.	.
epidermis; Ulceration		.	.	.	.	.	2	.	3	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	+	.	+	.	.	+	.	+	.	.	N	.	.	.
Hyperplasia; epidermal		.	3	.	3	.	.	3	.	3	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	2	.	2	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	2	.	.	2	.	2	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
subcutis; Edema		.	2	.	3	.	.	3	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	2	.	3	.	.	3	.	3	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	2	.	.	3	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	2	.	2	.	.	2	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	2	.	3	.	.	3	.	1	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	2	.	2	.	.	2	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	1	.	3	.	.	2	.	2	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	3	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	N	+	N	+	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	2	.	1	.	.	2
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	2	3	3	3	2	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	2	3	3	3	2	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	N	+	+	+	+	+	+	+	+
Congestion		3	3	2	2	2	3	.	3	2	2	3	3	3	3	2
Hematopoiesis; extramedullary		.	.	1	1	1	1	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	+	+	+	+	N	N	N	+	+	+	+	N	+	+
Ossification		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	2	1	.	.	.	.	.	.	.	.	.	3	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	1	1	1	.	.	.	1	1	1	.	.	1	1
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	2	1	1	1	1	2	1	1	1	1	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	1	1	2	1	2	2	2	2	2	3	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		.	1	1	2	1	1	2	2	2	1	2	1	1	2	2
Plasmacytosis		2	.	2	1	1	.	.	.	2	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	1	1	1	.	1	2	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	2	2	3	1	.	2	1	1	1	1	3	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	2	2	1	2	1	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	+	N	+	N	N	N	N	+	N	N	N	N	N	N
perineural; Inflammation		.	3	.	3	.	.	.	4	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
OPTIC NERVE, RIGHT;		N	N	N	X	N	N	N	N	X	X	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	X	X	N	N	
PARATHYROID, RIGHT;		N	X	N	X	N	N	N	X	N	N	X	N	X	N	N
PEYERS PATCHES;		+	X	+	+	X	+	X	N	X	+	X	+	+	X	+
Mineralization		.	.	.	2	.	.	.	.	.	.	.	.	.	.	
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
germinal center; Increased Cellularity		3	.	2	2	.	3	.	.	.	2	.	2	3	.	2
PITUITARY GLAND;		N	N	+	N	N	N	N	N	N	N	N	N	N	+	N
pars distalis; Cyst		.	.	1	.	.	.	.	.	.	.	.	.	2	.	
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
PROSTATE GLAND;		N	N	N	N	+	X	N	N	N	N	N	N	N	+	N
Infiltration; mixed		.	.	.	.	2	.	.	.	.	.	.	.	.	.	
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	2	.	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	+	+	+	+	+	+	+	+	+	+	N	+	+	
Congestion		1	1	1	1	1	2	1	1	1	1	2	.	1	1	
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Infiltration, Eosinophilic		1	1	1	1	1	.	1	1	1	1	2	1	1	2	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		1	.	.	.	.	1	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	X	N	
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	+	+	+	N	N	+	+	+	N	N	N	N	+	N
Hemorrhage; acute		1	2	1	1	.	.	1	1	2	.	.	.	.	2	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	+	+	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	1	1	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	5
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5			
URINARY BLADDER;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	+	N	+	N	+	N	+	N	N	+	N	N	N
Dilation; vascular		.	.	1	.	1	.	1	.	1	.	.	1	.	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	+	+	+	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		.	1	1	1	.	.	.	.	.	.	.	.	.	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		+	+	+	+	N	+	+	+	+	+	+	+	N	+	
Infiltration, Lymphocytic		1	1	1	1	.	1	1	1	1	2	1	1	.	1	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	N	+	N	+	+	+	N	+	+	+	+	+	+
Infiltration, Lymphocytic		1	1	.	1	.	1	1	1	.	1	1	1	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
HEART;		+	N	N	N	N	N	N	N	N	N	N	+	N	N	
Infiltration; lymphohistiocytic		3	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		.	2	3	2	3	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	.	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	3	3	3	3	3	3	2	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	1	1	1	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1	1
intramuscular / interstitial; Inflammation; mixed		2	2	2	2	2	3	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		.	1	1	1	1	2	1	1	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		2	2	2	3	3	3	3	3	2	2	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		3	.	3	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		+	N	N	N	N	+	N	N	N	N	+	+	+	+	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		2	.	.	.	.	1	.	.	.	.	2	2	3	2	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	+	N	N	N	+	N	N	N	+	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	1	.	.	.	2	.	.	.	2	.	.	3
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	2	3	2	3	2	2	3	3	3	3	3	3
Infiltration, Lymphocytic		.	1	.	.	1	.	.	.	.	1	.	.	.	1	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	2	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	2	3	2	2	2	2	3	3	3	3	3	2
Infiltration, Lymphocytic		.	1	.	1	.	.	.	.	.	1	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	3
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	3	3	3	3	2	2	.	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	1	1	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	1	1	1	.	.	1	.	.	.	1	1	1	1	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	+	+	+	+	N	N	+	+	N	N	+	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	2	2	.	2	1	.	.	1	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	.	.	1	1	.	.	.	.	1	.	.	1	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	1	1	1	1	1	.	1	2	1	1	1	2	1
Hemorrhage		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	1	1	1	2	2	2	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	1	1	2	2	1	1	2	2	1	1	2	2
Plasmacytosis		2	2	2	2	.	1	.	2	2	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
germinal center; Increased Cellularity		2	.	3	3	3	2	2	2	2	2	2	2	2	2	1
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	1	2	2	2	2	2	2	2	1	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	X	N	X	N	N	N	N	N	N	X	N	X	N	N
PARATHYROID, RIGHT;		N	N	N	N	N	X	N	N	X	X	N	X	N	N	N
PEYERS PATCHES;		+	+	+	+	X	+	+	+	+	+	+	+	+	+	X
Mineralization		.	.	.	.	.	1	.	.	1	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	2	2	3	.	3	3	3	3	3	3	3	3	2	.
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	+	N	+	N	N	N	N	N	N	+	+	N	+	
Infiltration; mixed		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	2	.	.	.	.	.	.	1	3	.	1	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	N	+	N	+	+	N	N	N	+	+	+	N	N	N
Congestion		1	.	1	.	1	1	.	.	.	.	2	1	.	.	.
Hematopoiesis; increased		1	.	.	.	1	.	.	.	.	1	.	.	.	.	.
STOMACH, GLANDULAR;		N	N	+	N	+	+	+	N	N	+	+	+	+	+	+
Infiltration, Eosinophilic		.	.	1	.	1	.	1	.	.	1	2	1	2	2	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	1	.	.	.	.	.	.	.	1
Cyst		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	N	N	+	+	+	N	N	+	+	+	N	+	N	N
Hemorrhage; acute		1	.	.	1	1	1	.	.	1	1	2	.	1	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
TRACHEA;		N	N	+	N	+	N	N	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	1	.	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	N	+	N	N	N	N	N	N	+	+	+	N	N
Dilation; vascular		.	.	.	1	.	.	.	.	.	.	1	1	1	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	N	N	N	+	N	+	+	N	N	+	+	+	N	+
Infiltration, Lymphocytic		.	.	.	.	1	.	1	1	.	.	1	1	1	.	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		N	+	N	N	+	+	+	+	+	N	+	+	+	+	N
Infiltration, Lymphocytic		.	1	.	.	1	1	.	1	1	.	1	1	1	1	.
Infiltration; mixed		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	N	+	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	1	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	+	N	N	N	N	+	N	+	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		3	3	2	2	2	2	.	2	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	.	2	2	1	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		4	3	3	3	3	3	2	3	4	3	.	.	.	.	.
subcutis; Edema		3	3	3	2	2	2	.	2	4	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	.	2	2	2	.	1	1	1	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
intramuscular / interstitial; Inflammation; mixed		3	3	3	3	3	3	2	3	3	3	.	.	.	.	.
intramuscular / interstitial; Edema		2	1	1	2	2	2	.	.	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	.	2	2	2	2	2	2	2	2
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		4	3	4	3	3	3	2	3	4	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	2	2	1
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		3	3	3	2	2	3	.	#	4	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	3	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL										1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	+	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	2	.	.	2	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	+	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	2	.	.	2	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL										1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	+	N	N	+	N	N	N	N	N	
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	1	.	.	2	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	2	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	.	1	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	1	.	1	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	2	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	3	3	3	3	2	3	3	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	1	1	1	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		2	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration, Neutrophilic		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	.	1	1	.	.	.	1	.	.	1	1	1	1	.
Vacuolation; hepatocellular		2	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Infiltration, Eosinophilic		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	+	+	N	+	+	+	+	+	N	+	+	
Ossification		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	1	1	1	.	.	.	.	.	2	.	.	2	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	1	.	1	1	.	1	1	1	2	1	.	.	1
perivascular; Infiltration, Eosinophilic		.	.	.	.	1	.	.	.	2	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	1	1	1	1	2	1	2	1	2	.	.	1	2
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	1	1	1	1	1	2	1	1	1	2	2	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	2	2	2	2	2	1	.	1	1	1	2	2
Plasmacytosis		3	2	2	.	3	3	3	3	3	3	1	.	1	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
germinal center; Increased Cellularity		2	2	2	1	2	2	2	2	2	2	2	1	3	1	1
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	3	2	2	2	3	2	2	1	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	1	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	3	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL										1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		X	X	X	X	X	N	X	X	X	N	N	N	N	N	N
PARATHYROID, RIGHT;		N	N	X	X	X	N	X	N	N	X	X	N	X	N	N
PEYERS PATCHES;		+	+	+	+	+	+	+	+	+	X	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	3	3	3	3	2	3	3	.	3	3	3	3	2
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	+	N	N	N	+	N	N	N	+	+	+	+
Infiltration; mixed		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Inflammation; purulent		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	2	1	2	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	+	+	+	N	+	+	+	+	+	N	+	+	N	N
Congestion		1	1	1	1	.	1	1	1	1	1	.	1	1	.	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	N	+	N	+	+
Infiltration, Eosinophilic		2	2	2	1	2	2	2	1	2	2	.	1	.	1	2
Infiltration, Lymphocytic		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1
	NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	3	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	N	N	+	N	+	+	N	N	+	N	N	+	N	N
Hemorrhage; acute		1	.	.	1	.	1	1	.	.	2	.	.	1	.	.
THYROID, LEFT;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	+	N	N	N	+	+	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	1	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
ANIMAL	.	.	.	.	.	.	.	.	.	.	1	1	1	1	1	1	1	1	1	1	1
NUMBER	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1
URINARY BLADDER;	N	+	N	N	X	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic	.	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	+	N	N	N	N	N	N	N	N	N	N	+	N	+
Dilation; vascular		.	1	.	.	.	.	.	.	.	.	.	.	1	.	1
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
ADRENAL GLAND, RIGHT;		+	N	N	N	N	+	N	N	N	N	N	N	N	+	N
Dilation; vascular		1	.	.	.	.	1	.	.	.	.	.	.	.	1	.
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		+	N	N	N	+	N	+	+	N	N	+	N	N	N	N
surrounding tissue; Inflammation; mixed		3	.	.	.	2	.	2	1	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		...	.	.	.	.	.	.	.	.	.	1	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	+	+	+	+	+	N	+	N	N	+	+	+	N	
Infiltration, Lymphocytic		.	1	1	1	1	1	1	.	1	.	.	1	1	1	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	+	+	+	N	+	+	+	N	+	+	N	+	N
Infiltration, Lymphocytic		1	1	1	1	1	.	1	1	1	.	1	1	.	1	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		+	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		2	3	2	2	3	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	1	2	2	2	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	2	3	3	3	2	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	.	3	3	3	.	3	3	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	.	2	2	2	1	2	2	2	1	1	1	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	1	.	1
intramuscular / interstitial; Inflammation; mixed		2	3	.	3	3	3	2	2	3	1	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	.	2	2	2	.	2	2	1	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	1	1
inter- / perimuscular; Inflammation; lymphocytic		.	.	3	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	3	1	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	1	1
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		3	3	.	3	3	3	.	3	3	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia; epidermal		3	3	2	3	3	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		4	2	2	4	4	3	2	3	3	3	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	2	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Edema		4	3	3	3	4	4	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	2	2	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	1	1	1
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	1	1	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	1	1	1
intramuscular / interstitial; Inflammation; mixed		2	3	2	3	3	2	2	2	3	3	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		+	+	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		1	1	.	.	1	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		+	+	N	N	+	N	N	N	N	N	N	+	N	N	+
Infiltration, Eosinophilic; increased		1	1	.	.	1	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		2	.	.	.	.	.	.	.	.	.	2	.	.	2	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		+	+	N	N	+	N	N	N	+	N	N	+	+	N	N
Infiltration, Eosinophilic; increased		1	1	.	.	1	.	.	.	.	.	.	.	1	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	2	.	.	2	2	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	3	3	3	2	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	3	2	2	3	2	3	3	3	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	1	1	.	.	.	.	.	.	1	1	1	.	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		1	1	2	1	.	1	.	2	2	1	.	.	.	.	.
kupffer cell; Pigmentation; brown		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		N	N	+	+	+	+	+	+	N	+	N	+	+	+	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	1	.	.	1	.	.	.	2	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	.	1	1	1	.	.	1	.	.	1	1	.
perivascular; Infiltration, Eosinophilic		.	.	1	1	.	1	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	1	2	1	1	1	2	2	2	1	1	1	2	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	2	2	1	2	2	2	2	2	2	1	2	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	1	1	1	2	2	2	2	2	2	1	2	2	2	3
Plasmacytosis		1	2	3	4	.	.	2	2	3	2	1	1	.	.	2
Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	2	.	.	3	.	2	2	3	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	2	2	2	2	2
germinal center; Increased Cellularity		2	1	2	2	2	2	2	2	3	3	2	2	2	1	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	1	2	2	2	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		+	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	+	N	N	N	N	N	+	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	3	.	.	.	.	.	2	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	N	+	N	+	N	+	N	N	N	N	N
perineural; Inflammation		1	1	2	1	.	3	.	3	.	2	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	2	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		+	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
PARATHYROID, RIGHT;		N	N	X	N	N	N	N	X	N	X	N	N	N	N	X
PEYERS PATCHES;		+	+	+	+	+	+	N	+	+	+	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	3	2	3	3	.	3	3	3	3	3	3	3	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	N	N	N	+	N	X	N	N	N	+	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	X	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	3	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	+	+	+	+	+	N	+	N	+	N	N	+	+	N
Congestion		.	1	1	1	1	.	.	1	.	1	.	.	1	1	.
Hematopoiesis; increased		2	.	.	.	.	2	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	N	+	+	+
Infiltration, Eosinophilic		2	1	1	1	2	1	2	1	1	1	2	.	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		+	+	N	N	+	+	N	N	N	N	N	+	N	N	+
Hemorrhage; acute		1	2	.	.	2	1	.	.	.	.	.	1	.	.	1
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		+	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		1	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	2	2	2	2	2	2	2	2	2	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	+
Dilation; vascular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	1
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	+
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	1	.	1
Vacuolation; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N	
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.	
BONE, STERNUM;		N	X	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	N	+	+	+	+	N	+	N	N	+	+	+	+	
Infiltration, Lymphocytic		.	.	1	1	1	1	1	.	1	.	.	1	1	1	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		N	N	+	+	+	+	+	+	N	N	+	+	+	+	+
Infiltration, Lymphocytic		.	.	1	1	1	1	1	1	.	.	1	1	1	1	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		+	N	+	N	N	N	N	N	+	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Necrosis		1	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.	
Infiltration; mixed		1	.	1	.	.	.	.	.	.	.	.	.	.	.	
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	N	+	+	+	+	+	N	N	N	N	
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)																
Hyperplasia; epidermal		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
myofiber; Necrosis		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	.	3	.	2	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	3	4	.	3	4	3	4	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	.	2	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		3	2	2	3	.	3	3	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	.	1	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	.	2	2	3	2	2	1	.	.	.	.
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		3	3	3	#	.	2	3	2	4	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)																
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	+	+	N	+	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	1	2	.	2	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	N	N	+	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	2	.	.	.	
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	2	.	.	1	.	.	.	.	1	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	1	.	.	.	.	.	2	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	N	+	+
Congestion		3	2	2	3	2	2	3	3	3	3	3	3	.	2	3
Hematopoiesis; extramedullary		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	1	.	.	.	.	.	.	1	.	.	.	.
Necrosis		.	1	.	.	.	.	.	.	.	4	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	1	
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	+	N	N	+	N	+	+	+	N	+	N	+	+	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	2	.	.	2	.	2	.	2
Infiltration; lymphohistiocytic		.	.	.	.	2	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	.	.	.	1	.	1	.	1	.	1	1	.	
perivascular; Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	.	2	1	1	2	2	1	1	1	1	2	2	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	1	2	2	2	1	2	1	1	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	2	2	2	2	1	2	2	1	2	.	2	1	1
Plasmacytosis		1	.	.	1	1	1	.	2	.	3	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	3	.	2	3	1	.	.	.	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	2	.	1	.
germinal center; Increased Cellularity		2	2	2	3	2	3	2	2	2	2	1	2	1	1	1
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		3	2	2	2	2	2	2	2	2	2	2	2	1	1	1
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	1	2	2	2	2	2	2	1	2	3	1	2
LYMPH NODE, RENAL;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		+	N	+	N	N	N	N	+	+	N	N	N	N	N	N
interstitium; Inflammation; mixed		3	.	2	.	.	.	.	2	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	3	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	X	N	N	X	N	N	N	X	N
PARATHYROID, RIGHT;		N	N	N	N	N	N	X	X	X	N	N	N	N	N	N
PEYERS PATCHES;		+	+	+	+	+	+	+	+	+	+	N	+	+	X	+
Mineralization		.	.	.	.	.	.	1	1	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	2	2	3	3	2	2	3	3	.	3	3	.	2
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	N	N	+	N	N	N	N	+	N	+	+	N
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	2	.	.	.	.	1	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	1	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		+	N	N	+	N	+	N	+	N	+	N	N	N	+	+
Congestion		1	.	.	2	.	1	.	1	.	1	.	.	.	1	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	N	+	N	+	+	N	+	N	+	+	+	+	N
Infiltration, Eosinophilic		1	1	.	1	.	1	.	.	1	.	2	1	1	1	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
mucosa; Infiltration, Neutrophilic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		N	N	N	+	+	N	N	+	+	+	+	+	N	+	N
Hemorrhage; acute		.	.	.	1	1	.	.	2	1	1	1	1	.	1	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	5	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5			
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N			
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
ADRENAL GLAND, LEFT;		N	+	N	N	N	N	+	N	N	N	N	+	N	+
Dilation; vascular		.	1	.	.	.	.	.	.	.	.	.	1	.	1
Vacuolation; cortical		.	.	.	.	.	.	2	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	+	N	N	N	+	N	N	+	N	+	N	N
Dilation; vascular		.	.	.	1	.	.	.	.	.	.	1	.	1	.	.
Vacuolation; cortical		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	+	N	N	N	+	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	2	.	.	.	2	.	.	.	.	.
surrounding tissue; Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIS, LEFT;		N	+	+	+	+	+	+	+	+	+	N	N	+	+	N
Infiltration, Lymphocytic		.	1	1	1	1	1	1	1	1	1	.	.	1	1	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
EPIDIDYMIS, RIGHT;		+	+	+	+	+	+	+	+	+	+	N	+	+	N	
Infiltration, Lymphocytic		1	1	1	1	1	1	1	1	1	1	.	1	1	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Oligospermia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
HARDERIAN GLAND, LEFT;		+	N	N	N	N	N	N	N	N	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; lymphohistiocytic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HEART;		N	N	N	N	N	N	N	N	N	N	+	+	N	N	
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	1	.	.	
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Hemorrhage		.	.	.	2	.	.	.	.	.	.	.	.	.	.	
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Hyperkeratosis; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE I; (Continued)															
Hyperplasia; epidermal		3	.	3	2	2	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		4	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	2	3	3	3	3	4	4	3	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	.	1	1	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	1	2
intramuscular / interstitial; Inflammation; mixed		3	2	3	2	3	3	3	2	2	3	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	1	2	2	2
inter- / perimuscular; Inflammation; lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		4	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	2	2
inter- / perimuscular; Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		4	3	3	3	3	3	4	4	4	3	.	.	.	.	.
inter- / perimuscular; Multinucleated Macrophages		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perivascular; Inflammation; plasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia; epidermal		3	.	3	2	3	.	3	3	3	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Ulceration; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INJECTION SITE II; (Continued)															
Hemorrhage		.	.	.	.	.	.	.	.	2	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis; traumatic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		4	3	3	3	4	3	4	3	3	#	.	.	.	.
subcutis; Fibrosis		2	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Edema		4	4	3	3	4	3	4	3	4	2	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	2	1	2
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	2	1	2
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	1	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	2	2	2	2	2	2	2	2	2	1	1	1	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	2	.	2
intramuscular / interstitial; Inflammation; mixed		2	2	3	3	3	3	2	3	3	2	.	.	.	.	.
dermis; subcutis; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	1	2
KIDNEY, LEFT;		+	+	+	+	+	N	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	.	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	1	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	1	1	.	.	.	.	.	.
tubule; Cast; hyaline		.	1	1	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	3	2	3	3	3	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	1	1	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	2	2	.	.	.	.	.	.	.	1	1	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcapsular; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	3	3	3	3	3	2	2	3	3	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	1	.	.	.	1	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Necrosis		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	1	1	.	.	.	1	.	.	.	.	1	1
Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	1	2	1	2	2	1	1	1	2	.	.	.	.	.
kupffer cell; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	N	N	N	+	+	N	+	+	+	N	+	N	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		2	.	.	.	.	.	2	.	.	2	1	.	.	.	1
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	.	.	1	.	.	1	.	.	.	1	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
macrophage; alveolus; Infiltration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	N	+	+	+	+	+	+
Histocytosis		1	1	1	2	2	2	1	.	.	2	2	1	2	1	1
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	3	3	1	3	.	2	2	2	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	.	2	2	1	2	1	2	2	1	1	1	1	2
Plasmacytosis		2	2	2	2	2	3	2	2	2	2	1	.	.	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	2	2	1	2	2	2	2	3	2	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	1	1	1	2
germinal center; Increased Cellularity		3	2	2	2	2	2	2	2	3	2	1	2	2	2	2
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	3	2	2	2	2	2	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	1	2	2	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, RENAL;		.	.	.	+	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Plasmacytosis		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	.	.	2	.	.	.	.	.	.	.	.	.	.	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
interstitium; lymphatic; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	+	N	N	+	N	+	+	N	+	N	N	N	N	N
Infiltration; mixed		.	1	.	.	1	.	1	1	.	1	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	1	1	.	1	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	+	+	+	+	+	+	N	N	N	+	+
perineural; Inflammation		3	3	2	4	3	3	1	4	3	2	.	.	.	1	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	X	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PANCREAS;		N	N	X	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	X	N	N	X	X	N	N	N	N	X	N	N	N	N
PARATHYROID, RIGHT;		N	N	N	X	X	N	N	N	X	N	N	N	N	N	N
PEYERS PATCHES;		+	+	+	+	+	+	+	X	+	+	+	X	+	+	X
Mineralization		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	3	3	2	3	3	.	2	3	3	.	3	2	.
PITUITARY GLAND;		N	N	+	N	+	+	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	1	.	1	2	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PROSTATE GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	2	3

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SEMINAL VESICLES;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; fat; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKIN;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Necrosis; muscular		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
Infiltration, Neutrophilic; muscular		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
subcutaneous; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPLEEN;		N	N	+	N	N	+	N	+	+	+	+	+	N	N	N
Congestion		.	.	1	.	.	1	.	1	1	.	1	1	.	.	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	1	1	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	1	1	1	1	1	.	1	1	1	1	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	2	.	.	.	.	.	.	.	.	.	2
mucosa; Infiltration, Neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTIS, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Spermatid Giant Cells		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TESTIS, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphoplasmacytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Spermatocoele		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYMUS;		N	+	+	+	N	+	N	N	+	N	+	+	N	N	N
Hemorrhage; acute		.	2	2	1	.	1	.	.	1	.	1	1	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: MALE

	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	+	N	+	+
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	1	.	1	1
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	+	N	N	N	+	N	N	N	N	
Dilation; vascular		.	.	.	.	.	1	.	.	.	1	.	.	.	.	
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Increased Cellularity		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		+	N	+	N	N	N	N	N	N	N	+	N	N	N	
Keratinization; epithelial		2	.	2	.	.	.	.	.	.	.	2	.	.	.	
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	2	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	N	+	N	N	N	N	+	N	N	N	N	N
Hemorrhage		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		1	.	1	.	.	.	.	.	.	1	.	.	.	.	.
Inflammation; mixed		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		N	+	N	N	+	+	+	N	N	+	N	N	N	N	N
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	1	1	1	.	.	1	.	.	.	.	.
Inflammation; mixed		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	N	N	N	N	+	N	N	N	N	+	N	+	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	3	3	2	3	3	2	3	3	2	3	3
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	1	.	.	.	.	1	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	3	2	3	3	2	3	3	2	3	3	2	3	3
Infiltration, Lymphocytic		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
pelvis; Inflammation; purulent		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	3	3	3	2	3	1	2	2	3	3	2	3	3
Hematopoiesis; extramedullary		.	1	.	.	1	.	.	.	1	.	.	.	.	.	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	3
	NUMBER	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
LIVER; (Continued)																			
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	1	1	1	.	1	1	1	.	.	1	1	.	.	.	.	.	.
periportal; Vacuolation; hepatocellular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LUNGS WITH BRONCHI;		N	+	N	N	N	+	N	N	N	N	+	N	N	N	N	+		
Ossification		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																			
Hyperplasia		.	.	.	.	.	1	.	.	.	.	1	.	.	.	.	.	.	.
perivascular; Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Histocytosis		1	1	2	1	1	1	1	1	.	1	1	1	1	1	1	1		
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.		
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.		
germinal center; Increased Cellularity		.	2	2	1	2	.	3	1	2	1	1	2	1	2	2			
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Histocytosis		2	2	1	2	2	2	2	2	.	2	1	1	1	1	1	1		
Plasmacytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.		
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.		
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.	.		
Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.		
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.		
germinal center; Increased Cellularity		.	.	.	.	.	1	1	1	.	2	1	1	2	.				

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	X	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	.	2	2	2	1	1	2	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	.	2	2	2	2	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	X	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	X
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	X	N	N	N	N	N	N	N	N	N	X	X
PEYERS PATCHES;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	3	2	3	3	3	3	3	3	2	3	3	3	2
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	X	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	+	+	+	+	N	N	+	N	+
Congestion		1	2	1	1	1	1	2	2	1	1	.	.	1	.	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	N	+	+	+	+
Infiltration, Eosinophilic		1	2	2	1	1	1	1	1	2	1	.	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	1	.	.	
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		N	+	+	+	+	+	N	+	N	+	N	N	N	N	+
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	2	1	1	1	1	.	1	.	1	.	.	.	.	2
THYROID, LEFT;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	1	1	1	1	2	2	2	2	2	2	2	2	2	2	3
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	+	N	N	N	N	N	N	N	N	+	N	N	N	
Infiltration, Lymphocytic		.	1	.	.	.	.	.	.	.	.	1	.	.	.	
UTERUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
VAGINA;		+	N	+	N	N	+	N	N	N	N	N	+	N	N	N
Keratinization; epithelial		2	.	2	.	.	1	.	.	.	.	.	2	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
ADRENAL GLAND, LEFT;		+	N	+	N	N	N	N	N	N	+	N	N	N	N
Dilation; vascular		1	.	1	.	.	.	.	.	.	1	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	+	N	N	N	N	N	N	N	+	N	N	N	N
Dilation; vascular		.	1	.	.	.	.	.	.	.	1	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		+	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		1	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		+	N	N	+	+	+	N	N	N	N	+	N	+	+
Keratinization; epithelial		2	.	.	2	2	2	.	.	.	.	1	.	2	2
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		+	N	N	N	N	+	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		1	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	2	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	+	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	2	.	.
HEART;		N	N	N	+	N	+	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	1	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	3	.	3	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	2	.	.	1	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	.	2	.	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	.	1	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	1	.
intramuscular / interstitial; Inflammation; mixed		2	2	2	2	2	3	2	2	2	3	.	.	.	.	.
intramuscular / interstitial; Edema		2	1	1	2	1	1	1	1	1	1	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	1	.
inter- / perimuscular; Edema		3	3	3	2	3	3	3	3	3	3	.	.	.	.	.
epidermis; Ulceration		.	.	.	3	3	.	.	3	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	+
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
INJECTION SITE II; (Continued)															
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	1
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	2
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	+	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	3	.	.	.
INTESTINE, COLON;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	N	N	N	N	N	N	+	N	+	+	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	2	.	2	1	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	3	3	2	2	3	2	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	1	.
Mineralization		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	3	2	3	3	2	2	2	2	2	3	3	3	2	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	2	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	2	3	3	3	2	2	2	2	3	3	3
Hematopoiesis; extramedullary		.	.	.	.	.	.	1	1	1	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	1	.	1	1
periportal; Vacuolation; hepatocellular		1	2	2	2	2	1	1	2	1	2	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	+	N	N	N	N	+	N	N	+	+	+	N	+
Ossification		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	2	2	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		1	.	1	.	.	.	.	.	.	.	1	.	.	.	1
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	2	1	1	1	.	2	1	1	2	2	2	1	2	.
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	1	2	2	2	2	2	2	2	2	2	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	.	1	1	1	1	1	1	1	1	1	1	2	1
Plasmacytosis		.	1	.	.	.	.	2	.	.	1	.	2	1	.	1
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	.	.	1	2	2	.	2	2	2	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	1	1	.	.
germinal center; Increased Cellularity		.	.	2	3	2	2	2	2	2	1	2	2	1	2	1

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		3	1	1	2	2	2	2	2	2	3	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	1	2	2	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	+	N	N	N	N	+	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	2	.	.	.	.	1	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	+	N	N	N	X	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	+	N	N	N	N	N
Fibrosis; interstitial		.	.	.	.	.	.	.	.	2	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PEYERS PATCHES;		+	X	X	+	X	+	+	+	+	X	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	.	.	2	.	2	3	3	3	.	3	3	3	3
PITUITARY GLAND;		N	+	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	1	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	+	+	N	+	+	N	N	+
Congestion		1	1	2	2	1	1	2	1	1	.	1	1	.	2
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	N	N	+	+	+	N	+	+	+	+	+	+
Infiltration, Eosinophilic		.	1	.	.	1	1	1	.	1	.	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		1	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	2	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	1	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	+	+	N	+	+	N	+	+	+	N	+	N	N	+
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	1	2	.	2	2	.	1	1	1	.	1	.	.	1
THYROID, LEFT;		N	N	+	N	+	N	N	N	N	+	N	N	N	N	N
Cyst; keratinized		.	.	1	.	1	.	.	.	.	1	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	4	4	4	4	5	5	5	5	5	5	5	5	5	6
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	+	N	N	N	N	+
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	1
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	1	.	.	.	.	.
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		+	N	N	N	+	+	N	N	N	N	N	N	N	N
Dilation		2	.	.	.	2	2	.	.	.	.	.	.	.	.
VAGINA;		+	N	N	+	+	+	+	N	N	N	N	+	N	+
Keratinization; epithelial		2	.	.	2	2	2	1	.	.	.	.	1	.	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		N	N	+	+	N	+	N	N	N	N	N	+	+	+	
Dilation; vascular		.	.	1	.	.	1	.	.	.	.	.	1	1	1	
Hypertrophy; cortical		.	.	.	2	.	.	.	.	.	.	.	.	.	.	
ADRENAL GLAND, RIGHT;		N	N	N	+	N	+	N	N	N	N	N	N	N	N	
Dilation; vascular		.	.	.	.	.	1	.	.	.	.	.	.	.	.	
Hypertrophy; cortical		.	.	.	2	.	.	.	.	.	.	.	.	.	.	
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	
surrounding tissue; Inflammation; mixed		.	.	.	.	1	.	.	.	.	.	.	.	.	.	
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		N	N	N	+	N	N	N	+	N	+	+	+	N	N	N
Keratinization; epithelial		.	.	.	2	.	.	.	2	.	2	1	2	.	.	.
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		+	N	+	N	+	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	1	.	.	.	.	.	.	2	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		2	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	+	N	+	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	1	.	1	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	3	2	2	3	2	3	3	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	.	2	2	2	.	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	.	3	4	4	3	3	3	3	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	.	.	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
intramuscular / interstitial; Inflammation; mixed		2	3	3	3	2	3	3	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		2	2	1	.	2	2	2	2	2	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	2	1	1	1
inter- / perimuscular; Inflammation; mixed		3	4	3	3	4	4	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	1	1
inter- / perimuscular; Edema		3	3	3	3	4	3	3	3	3	1	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	0
INJECTION SITE II; (Continued)														
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	+	N	N	N	N	N	N	+
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	2	.	.	.	.	.	.	2
INTESTINE, COLON;		+	N	N	N	N	+	N	N	N	N	N	+	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		2	.	.	.	.	2	.	.	.	.	.	2	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
INTESTINE, RECTUM;		N	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	1	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	3	3	3	2	2	3	3	3	3
Infiltration, Lymphocytic		.	.	1	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	2	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	1	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	3	2	3	3	3	2	2	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	1	.	.	.	1	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	X	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	2	2	3	2	3	2	2	3	2	2
Hematopoiesis; extramedullary		1	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		1	.	.	1	.	.	.	.	.	1	1	1	1	.	1
periportal; Vacuolation; hepatocellular		1	2	1	.	.	1	.	1	1	.	.	.	.	.	.
LUNGS WITH BRONCHI;		+	N	N	N	+	+	+	N	+	N	N	N	+	N	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	.	.	1	2	1	.	1	.	.	.	.	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	1	.	.	.	.	.	1	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	2	1	2	1	2	1	1	2	2	1	2	2	2
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	3	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	.	.	2	.	.	2	2	1	2	1	1	1	2	1
Plasmacytosis		2	2	1	2	2	.	.	.	2	2	.	1	.	1	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		.	1	.	.	2	.	.	.	.	2	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	2	1	2	2	2	2	3	2	2	1	3	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	2	2	2	1	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
MAMMARY GLANDS;		+	N	N	N	+	N	N	+	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		2	.	.	.	1	.	.	2	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	+	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	+	N	N	N	N	+	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	1	.	.	.	.	1	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	X	N	N	N	X	X	X	N	X	X	X	X
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	X	N	N	X	N	X	N	N	X	N	X	N	N	N
PEYERS PATCHES;		+	X	+	+	N	+	X	+	+	+	+	+	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	2	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	2	.
germinal center; Increased Cellularity		3	.	3	3	.	3	.	3	3	3	2	3	3	3	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	+	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		N	N	N	+	+	N	N	+	+	N	+	+	+	N	+
Congestion		.	.	.	.	1	.	.	1	2	.	2	1	1	.	2
Hematopoiesis; increased		.	.	.	1	.	.	.	1	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		N	+	+	+	N	N	+	N	+	N	N	+	+	+	+
Infiltration, Eosinophilic		.	1	1	.	.	.	1	.	1	.	.	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	1	.	.	.	.	1	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		N	N	N	N	N	+	N	N	N	+	+	N	N	N	N
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	1	.	.	.	1	1	.	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	X
Cyst; keratinized		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	NUMBER	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	N	N	N	N	N	N	N	N	+	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		+	N	N	+	N	N	+	N	N	+	N	+	N	N	N
Dilation		2	.	.	2	.	.	2	.	.	2	.	2	.	.	.
VAGINA;		N	+	N	+	N	N	+	+	N	+	+	+	N	N	N
Keratinization; epithelial		.	1	.	2	.	.	1	2	.	2	1	2	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	+	+	N	N	+	N
Dilation; vascular		.	.	.	.	.	.	.	.	.	1	1	.	.	1	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+	+
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	1	1
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		+	N	N	N	N	N	N	N	N	+	N	+	+	+	
Keratinization; epithelial		2	.	.	.	.	.	.	.	.	2	.	2	1	2	
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	+	N	N	+	N	N	N	+	N	+	N	N	N
Infiltration, Lymphocytic		.	.	1	.	.	.	.	.	.	.	2	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	3	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
INJECTION SITE I; (Continued)																			
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		2	.	3	.	2	2	2	2	2	.	.	.	.	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	1	2	2	2	2	2	2	1	.	.	.	.	.	.	.	.	.
dermis; subcutis; Inflammation;																			
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic ...		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	.	.	.	.	.	.	.	.	.
subcutis; Edema		3	2	3	2	2	3	2	3	3	3	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	1	1	1	.	1				
intramuscular / interstitial; Inflammation;																			
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	2	1	1	.	2	
intramuscular / interstitial; Inflammation;																			
mixed		3	2	2	2	3	3	3	3	2	3	.	.	.	.	.			
intramuscular / interstitial; Edema		2	1	2	.	2	2	1	2	2	2	.	.	.	.	.			
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	2	1	2			
inter- / perimuscular; Inflammation; mixed		3	3	4	3	3	3	3	3	3	3	.	.	.	.	.			
inter- / perimuscular; Inflammation;																			
lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	2	2	2	1	2	
inter- / perimuscular; Edema		3	3	4	2	3	3	3	3	3	3	3	.	.	.	.			
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
INJECTION SITE II;																			
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	+	N	N	N	N	N	N	+	N	N	N	+	N	
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	.	.	1	.	.	.	.	.	
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	1	.	
INTESTINE, COLON;		N	+	N	N	N	N	N	N	+	N	N	N	N	N	
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	.	.	1	.	.	.	.	.	
mucosa-associated lymphoid tissue; Hyperplasia		.	2	.	.	.	.	.	.	2	.	.	.	.	.	
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		+	+	N	+	N	+	N	N	N	+	N	+	N	N	N
Infiltration, Eosinophilic; increased		1	1	.	1	.	1	.	.	.	1	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	N	+	+
Congestion		3	2	2	3	3	3	3	3	2	3	3	3	.	3	3
Infiltration, Lymphocytic		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	2	3	3	3	3	3	2	3	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	3	3	2	2	2	3	2	2	3	3	3	3	3
Hematopoiesis; extramedullary		1	.	.	1	.	1	1	1	1	1	.	.	.	.	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
LIVER; (Continued)																			
Infiltration; mixed						1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic						1	1	1	1	.	.	.	.	.	1	1	.	.	.
periportal; Vacuolation; hepatocellular						1	2	2	2	2	2	2	2	1	.	.	.	.	.
LUNGS WITH BRONCHI;		N	+	N	+	+	+	+	+	+	N	+	N	+	N	+			
Ossification																			
Hemorrhage; acute											1								
Infiltration; mixed																			
bronchial-associated lymphoid tissue;																			
Hyperplasia								.	.	.	1	.	1	1	.	1	.	1	1
perivascular; Infiltration, Eosinophilic								2	.	.	2	1	.	1	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy								.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown								.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Histocytosis		1	1	1	1	1	1	1	1	1	1	1	1	1	2	.	1		
Erythrophagocytosis																			
macrophage; Pigmentation; brown																			
germinal center; Increased Cellularity		1	1	2	.	1	1	1	2	1	1	2	3	2	2	2			
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Histocytosis		2	1	2	.	1	1	1	.	1	.	.	1	2	1	.			
Plasmacytosis		2	3	.	3	3	.	3	3	3	3	1	1	.	.	1			
Infiltration, Eosinophilic																			
Hemorrhage; acute																			
Inflammation																			
Infiltration; macrophage															2	1	.	.	1
germinal center; Increased Cellularity		2	1	.	1	2	.	2	3	2	3	2	2	2	1	2			

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	1	2	2	2	2	2	2	2	2	2
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	N	+	N	+	N	N	N	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		2	2	.	2	.	1	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	X	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	+	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		X	N	N	N	N	N	N	N	N	N	N	N	N	X	N
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	N	X	N	N	N	N	N	N	N	N	N	X
PEYERS PATCHES;		+	+	+	X	+	+	+	+	X	+	N	N	+	+	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	2	.
germinal center; Increased Cellularity		3	3	3	.	2	3	3	3	.	2	.	.	3	3	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	X	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	N	+	+	+	N	+	+	+	N
Congestion		1	1	2	1	1	1	.	1	1	1	.	1	2	1	.
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		2	2	1	2	1	2	1	2	1	2	1	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		N	N	N	+	+	+	N	N	N	+	+	N	N	N	+
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	1	1	2	.	.	.	1	1	.	.	.	1
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	+	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	+	N	N	N	+	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	1	.	.	.	1	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		+	N	N	+	N	N	N	N	N	N	N	N	N	N	N
Dilation		2	.	.	2	.	.	.	.	.	.	.	.	.	.	.
VAGINA;		+	N	N	N	N	N	N	N	N	N	+	N	+	+	+
Keratinization; epithelial		2	.	.	.	.	.	.	.	.	.	2	.	2	1	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ADRENAL GLAND, LEFT;		+	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	+	N	N	N	N	N	N	+	N	N	N	N	N	N
Dilation; vascular		.	1	.	.	.	.	.	.	1	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	+	N	+	N	+	+	+	+	N	+	N	N	N	N
surrounding tissue; Inflammation; mixed		.	2	.	2	.	3	1	2	1	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		N	N	N	N	N	+	N	N	N	N	N	+	+	+	N
Keratinization; epithelial		.	.	.	.	.	1	.	.	.	.	.	2	2	2	.
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N	+
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)																
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	3	3	2	3	3	3	3	.	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		1	1	2	2	2	2	2	2	2	2	.	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
subcutis; Edema		3	2	2	3	3	3	3	3	3	3	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	1	2	2	2	2	2	2	2	2	1	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		2	2	2	2	3	2	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Edema		2	1	2	2	2	2	2	2	2	2	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	1	1	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	1	2	1	.
inter- / perimuscular; Edema		3	2	2	3	3	3	3	3	4	4	.	.	.	.	.
epidermis; Ulceration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	N	+	+	
Hyperplasia; epidermal		3	2	3	2	3	3	3	3	3	3	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		1	2	2	1	2	2	2	2	2	2	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		3	3	3	2	3	3	3	3	3	3	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	2	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Edema		3	3	3	3	3	3	3	4	3	3	.	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	1	.	1	1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	3	.	.	1	2
intramuscular / interstitial; Edema		2	2	2	1	2	2	2	3	2	2	.	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	.	.	.	1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	.	.	.	2
intramuscular / interstitial; Inflammation; mixed		2	2	3	2	3	3	2	2	2	3	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	+	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	1	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	+	N	N	N	N	N	N	N	+	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	2	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	+	N	N	+	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	1	.	.	1	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	2	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	3	2	2	3	3	3	2	3	2	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	2	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	3	2	2	2	3	3	3	2	3	2	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	2	2	3	3	3	2	3	3	3	3	2	3	3
Hematopoiesis; extramedullary		1	.	1	.	.	.	1	.	1	1	.	.	.	.	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
LIVER; (Continued)																			
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.	1	.	.
periportal; Vacuolation; hepatocellular		2	2	2	1	2	2	2	2	2	2	.	.	.	.	.			
LUNGS WITH BRONCHI;		+	N	+	N	N	+	+	+	+	+	N	+	N	N	+			
Ossification		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.			
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.			
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1			
bronchial-associated lymphoid tissue;																			
Hyperplasia		1	.	1	.	.	.	.	.	.	1	.	.	1	.	.			
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	1	.	2	.	.	.	.	.	.			
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.			
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Histocytosis		1	2	2	2	2	2	1	1	1	2	2	1	1	2	2			
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
macrophage; Pigmentation; brown		.	1	1	.	.	.	.	.	.	.	.	.	.	.	1			
germinal center; Increased Cellularity		2	1	2	2	2	2	1	2	2	2	2	2	2	2	2			
LYMPH NODE, ILIAC;		X	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Histocytosis		.	2	2	2	2	2	2	2	2	2	2	1	2	2	2			
Plasmacytosis		.	2	3	3	2	3	2	3	3	2	2	1	1	2				
Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.			
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
Inflammation		.	1	2	3	3	2	1	.	2	.	.	.	.	.	.			
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	3	1	2	2	1	
germinal center; Increased Cellularity		.	3	2	2	2	3	2	3	2	2	2	2	3	3				

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	1	2	2	2	2	2	2	2	2
Infiltration, Eosinophilic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	1	2	2	.
MAMMARY GLANDS;		N	N	N	+	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		+	+	N	N	N	N	N	+	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		1	.	.	.	.	.	.	1	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	+	+	+	+	+	N	+	N	N	N	
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		3	3	3	3	3	2	3	2	3	1	.	2	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	X	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	X	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	+	X	N	N	N	X	X	N	N	N	X	N	X
Fibrosis; interstitial		.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		N	N	N	X	N	N	X	X	X	N	X	N	N	X	X
PEYERS PATCHES;		+	X	+	+	+	+	X	+	+	+	+	+	+	X	+
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
germinal center; Increased Cellularity		2	.	3	3	3	3	.	3	3	3	3	3	3	.	3
PITUITARY GLAND;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	+	+	+	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	3	2	2	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	N	+	+	+	+	N	N	+	+	N	N	+	N
Congestion		.	1	.	.	.	1	1	.	.	1	1	.	.	1	.
Hematopoiesis; increased		2	1	.	1	2	2	1	.	.	1	.	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration, Eosinophilic		1	1	1	2	2	1	1	2	2	1	1	1	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	.	1	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	1	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	N	N	+	+	+	N	N	+	N	N	N	N	N	N
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	.	.	1	1	1	.	.	1	.	.	.	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	+	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	N	+	N	N	X	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		N	N	N	N	N	N	N	N	N	N	N	+	N	N	N
Dilation		.	.	.	.	.	.	.	.	.	.	.	3	.	.	.
VAGINA;		N	N	N	N	N	+	+	N	N	N	N	+	+	+	+
Keratinization; epithelial		.	.	.	.	.	1	1	.	.	.	.	2	2	2	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 6 6	1 6 7	1 6 8	1 6 9	1 7 0	1 7 1	1 7 2	1 7 3	1 7 4	1 7 5	1 7 6	1 7 7	1 7 8	1 7 9
ADRENAL GLAND, LEFT;		N	N	N	N	+	N	N	N	N	N	N	+	N	N	N
Dilation; vascular		.	.	.	.	1	.	.	.	.	.	.	1	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE, OS FEMORIS WITH JOINT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	N
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.	.
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CERVIX;		N	N	N	+	+	N	N	N	N	+	+	+	N	N	N
Keratinization; epithelial		.	.	.	2	2	.	.	.	.	2	2	2	.	.	.
Cyst; keratinized		.	.	.	.	.	.	.	.	.	3	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	+	N	+	+	+	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	2	.	.	.	.	.	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	2	.	2	.	.	.	.	.	.	.	.
Inflammation; purulent		.	2	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	1
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	+	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	+	N	+
Hemorrhage		.	.	.	.	.	.	2	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	3	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE I; (Continued)															
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	3	3	3	3	3	3	3	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	.	.	2	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	3	.	2	3	3	3	3	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
subcutis; Edema		3	3	4	3	3	4	4	4	4	3	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		3	2	2	3	3	2	3	3	3	3	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	1	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	1	.	1
inter- / perimuscular; Inflammation; mixed		3	3	3	4	4	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	1	.	.
inter- / perimuscular; Edema		3	3	4	3	2	3	3	3	3	3	.	.	.	.
epidermis; Ulceration		.	3	.	.	.	.	.	3	.	.	.	.	.	.
INJECTION SITE II;		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INJECTION SITE II; (Continued)																
subcutis; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Edema		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
intramuscular / interstitial; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	N	N	+	N	N	+	+	N	N	+	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	3	.	.	2	1	.	.	2	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	1	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	3	2	2	2	3	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	1	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	2	3	2	2	2	3	2	3	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
Mineralization		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	3	2	2	2	2	2	2	3	2	3	3	2	3	3
Hematopoiesis; extramedullary		1	1	1	1	.	.	1	.	.	1	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LIVER; (Continued)																
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	1	1	1	1	1	.
periportal; Vacuolation; hepatocellular		1	1	1	2	2	1	2	2	1	1	.	1	.	.	.
LUNGS WITH BRONCHI;		N	N	+	N	N	+	N	+	+	+	N	N	N	N	N
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	2	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
bronchial-associated lymphoid tissue;																
Hyperplasia		.	.	1	.	.	1	.	1	1	1	.	.	.	.	.
perivascular; Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		1	1	2	2	2	.	1	2	2	.	1	1	1	1	1
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
germinal center; Increased Cellularity		2	3	2	2	1	2	2	2	2	2	2	2	1	2	2
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Histocytosis		2	2	1	2	1	2	2	2	2	2	1	1	1	2	2
Plasmacytosis		2	.	2	2	2	2	1	.	.	2	.	.	1	.	.
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation		1	2	2	2	.	3	.	.	1	3	.	.	.	.	.
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	1	1	1	1	1
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	.	1	1	1

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	2
MAMMARY GLANDS;		N	N	N	N	+	N	N	+	+	N	N	+	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	2	.	.	3	3	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		N	N	N	N	N	N	N	N	N	N	N	X	N	N	N	N	N	N
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, LEFT;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
OVARY, LEFT;		N	N	N	N	N	X	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	X	N
Fibrosis; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		X	X	N	N	N	N	N	N	N	N	N	X	N	N	
PEYERS PATCHES;		+	+	X	+	+	X	+	X	+	+	+	+	+	X	+
Mineralization		.	1	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		3	3	.	3	3	.	2	.	1	2	3	3	3	.	3
PITUITARY GLAND;		N	N	N	N	+	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	X	N	N	N	N	N	N	N	N	N
SKIN;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
dermis; subcutis; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPINAL CORD;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	N	+	+	N	N	+	+	+	+	+	+	+
Congestion		1	1	2	.	1	1	.	.	1	1	1	1	1	2	1
Hematopoiesis; increased		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, GLANDULAR;		N	N	+	N	N	N	N	+	+	+	+	N	+	+	+
Infiltration, Eosinophilic		.	.	1	.	.	.	.	.	1	1	1	.	1	1	1
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	.	.	.	.	.	.	.	.	1	.	.	.	.	.
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	2	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	N	+	N	N	+	N	N	+	+	+	N	N	+	N
Cyst		.	.	2	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	.	.	.	.	1	.	.	1	2	2	.	.	1	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	X	N	N	N	N	N	+	N	N	N	N	N	+	N
Cyst; keratinized		.	.	.	.	.	.	.	1	.	.	.	.	.	1	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	NUMBER	6	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	8
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.
TRACHEA;		N	N	N	N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
URINARY BLADDER;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
UTERUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dilation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
VAGINA;		N	+	N	+	+	N	N	N	N	+	+	+	N	N	N			
Keratinization; epithelial		.	1	.	2	2	.	.	.	.	2	2	2	.	.	.			

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
ADRENAL GLAND, LEFT;		+	N	N	N	N	N	N	+	N	N	N	N	+	N				
Dilation; vascular		1	.	.	.	.	.	.	.	1	.	.	.	.	1				
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.				
ADRENAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	+				
Dilation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	1				
Hypertrophy; cortical		.	.	.	.	.	.	.	.	.	.	.	.	.	.				
AORTA ABDOMINALIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N				
BONE, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	N	+	+	+	N	N	N	N				
surrounding tissue; Inflammation; mixed		2	2	3	2	3	2	.	2	2	2	.	.	.	.				
surrounding tissue; Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.				
BONE MARROW, OS FEMORIS WITH JOINT;		+	+	+	+	+	+	+	+	+	+	N	N	N	N				
Increased Cellularity		1	1	1	1	1	1	1	1	1	1	.	.	.	.				
BONE, STERNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N				
surrounding tissue; muscle; Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.				
BRAIN, BRAIN STEM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N				
BRAIN, CEREBELLUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N				
BRAIN, CEREBRUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N				
CERVIX;		X	N	N	+	N	N	N	N	N	N	N	N	+	N	+			
Keratinization; epithelial		.	.	.	2	.	.	.	.	.	.	.	.	1	.	2			
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 6	1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1
ESOPHAGUS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYE, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
EYE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
HARDERIAN GLAND, LEFT;		N	N	N	N	N	N	N	N	N	+	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	2	.	.	.	.
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HARDERIAN GLAND, RIGHT;		N	N	N	+	+	N	N	N	N	+	+	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	2	1	.	.	.	.	1	2	.	.	.
Inflammation, Chronic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
HEART;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INJECTION SITE I;		+	+	+	+	+	+	+	+	+	+	+	N	+	+
Hemorrhage		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; granulomatous		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; vascular		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 9 6	1 9 7	1 9 8	1 9 9	2 0 0	2 0 1	2 0 2	2 0 3	2 0 4	2 0 5	2 0 6	2 0 7	2 0 8	2 1 0
INJECTION SITE I; (Continued)															
Foreign Material; hair		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hyperplasia; epidermal		3	3	3	2	3	3	3	3	3	3	.	.	.	.
Scab; epidermal		.	.	.	.	.	.	1	.	.	.	.	.	.	.
Pustule; epidermal		.	.	.	.	.	1	.	.	.	.	.	.	.	.
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	2	2	2	2	.	.	.	.
dermis; subcutis; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
dermis; epidermis; Inflammation; neutrophilic		.	.	.	.	.	2	.	.	.	.	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
subcutis; Edema		4	3	3	2	3	3	3	2	3	3	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	.	1 1
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	1	1	.	2 2
intramuscular / interstitial; Inflammation; mixed		2	2	3	2	2	2	2	2	2	2	.	.	.	.
intramuscular / interstitial; Edema		2	2	2	2	2	2	2	2	2	2	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	2	2	.	2 2
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	.	2 2
inter- / perimuscular; Edema		4	4	4	3	#	4	3	3	3	3	.	.	.	.
epidermis; Ulceration		2	.	.	.	.	.	1	.	.	.	.	.	.	.
INJECTION SITE II;		+	+	+	+	+	+	+	+	+	+	+	N	+	+
Hyperplasia; epidermal		3	3	2	3	3	3	.	2	3	2	.	.	.	.
Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
myofiber; Degeneration		2	2	2	2	2	2	1	1	2	2	.	.	.	.
myofiber; Necrosis		.	.	.	.	1	.	.	.	.	.	.	.	.	.
muscle; Regeneration		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 9 6	1 9 7	1 9 8	1 9 9	2 0 0	2 0 1	2 0 2	2 0 3	2 0 4	2 0 5	2 0 6	2 0 7	2 0 8	2 1 0
INJECTION SITE II; (Continued)															
subcutis; Edema		4	3	3	2	4	3	1	1	3	4	.	.	.	.
subcutis; Inflammation; mixed		3	3	3	3	3	3	2	2	3	3	.	.	.	.
inter- / perimuscular; Edema		4	3	3	3	4	4	2	2	3	4	.	.	.	.
inter- / perimuscular; Fibrosis		2	2	2	2	2	2	2	2	2	2	1	1	.	2 1
inter- / perimuscular; Inflammation; mixed		3	3	3	3	3	3	3	3	3	3	.	.	.	.
inter- / perimuscular; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	.	2 1
intramuscular / interstitial; Edema		2	2	2	2	2	2	1	1	2	2	.	.	.	.
intramuscular / interstitial; Fibrosis		2	2	2	2	2	2	2	2	2	2	.	1	.	1 .
intramuscular / interstitial; Inflammation; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	2	2	.	2 .
intramuscular / interstitial; Inflammation; mixed		2	2	3	2	2	2	2	2	2	2	.	.	.	.
dermis; subcutis; Fibrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, CECUM;		N	N	+	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	1	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, COLON;		N	N	+	N	N	N	N	N	N	+	N	N	N	N
Infiltration, Eosinophilic; increased		.	.	1	.	.	.	.	.	.	1	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
INTESTINE, DUODENUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, ILEUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
INTESTINE, JEJUNUM;		N	N	N	N	N	N	N	N	N	N	N	N	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
INTESTINE, RECTUM;		+	N	+	+	+	N	N	N	+	+	+	N	N	N	+
Infiltration, Eosinophilic; increased		1	.	1	1	.	.	.	.	1	1	1	.	.	.	.
Nematodiasis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	1	.	.	.	.	.	.	.	.	.	2
KIDNEY, LEFT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	3	3	2	2	2	3	2	3	2	3	3	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	.	.	.	1	.	.	.	.	.	.	.	.	.	.
Cyst; tubular		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Inflammation, Chronic; interstitial		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	1	.	.
tubule; Degeneration; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
KIDNEY, RIGHT;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		3	2	3	3	2	2	2	3	2	2	2	3	2	3	3
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Mineralization		.	1	.	.	.	1	.	.	.	.	.	.	.	.	.
Pyelonephritis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Basophilia		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
tubule; Cast; hyaline		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
pelvis; Inflammation; purulent		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
LACRIMAL GLAND, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LACRIMAL GLAND, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
LIVER;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Congestion		2	2	2	3	2	2	2	2	2	2	2	3	2	2	3
Hematopoiesis; extramedullary		.	.	1	1	1	1	.	.	.	1	.	.	.	.	.

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(b) (4)

Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE

	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
LIVER; (Continued)																			
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	2	.	.	
Infiltration, Lymphocytic		.	1	.	.	.	.	.	1	.	.	.	.	.	.	.	.	.	
periportal; Vacuolation; hepatocellular		2	1	2	2	2	2	2	1	2	.	.	.	.	.	.	.	.	
LUNGS WITH BRONCHI;		+	N	+	+	N	+	+	+	+	+	+	+	N	+	N	+	N	+
Ossification		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	2	.	.	.	.	.	.	
bronchial-associated lymphoid tissue;																			
Hyperplasia		1	.	.	1	.	1	.	1	.	.	.	.	.	.	.	.	1	
perivascular; Infiltration, Eosinophilic		1	.	1	1	.	1	1	.	1	.	.	.	.	1	.	.	1	
macrophage; alveolus; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	.	.	
LYMPH NODE, CERVICAL;		+	+	+	+	+	+	+	+	+	+	+	+	+	X	+	+		
Histocytosis		1	.	2	1	2	2	2	2	1	2	1	1	.	2	1			
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	.	.	2	2	.	2	2			
LYMPH NODE, ILIAC;		+	+	+	+	+	+	+	+	+	+	+	+	+	X	+	+		
Histocytosis		2	2	1	1	1	.	1	2	2	1	1	.	1	2				
Plasmacytosis		3	3	2	3	3	2	3	3	3	3	2	2	.	1	2			
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.			
Inflammation		.	2	2	2	2	.	.	.	2	1	.	.	.	.	.			
Infiltration; macrophage		.	.	.	.	.	.	.	.	.	.	.	.	2	2	.	3	2	
germinal center; Increased Cellularity		3	3	2	2	3	3	2	2	2	3	3	2	.	2	2			

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
LYMPH NODE, MESENTERIC;		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erythrophagocytosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Histocytosis		2	2	2	2	2	2	2	2	2	3	1	2	2	2	2
Infiltration, Eosinophilic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation		.	.	.	.	.	.	.	.	.	.	.	.	2	.	.
germinal center; Increased Cellularity		2	2	2	2	2	2	2	2	2	2	2	2	.	2	.
MAMMARY GLANDS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
interstitium; Inflammation; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
SKELETAL MUSCLE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	+
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.	1
myofiber; Necrosis		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
NERVE, SCIATIC;		+	+	+	+	+	+	+	+	+	+	N	N	N	N	+
Vacuolation		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
perineural; Inflammation		2	3	4	3	3	2	2	1	3	3	.	.	.	.	1
OPTIC NERVE, LEFT;		N	N	+	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	1	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
OPTIC NERVE, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Pigmentation; brown		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
macrophage; Infiltration; foamy		.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 6	1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1
OVARY, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVARY, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
OVIDUCT, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
PANCREAS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
acinar cell; Atrophy		.	.	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, LEFT;		N	+	N	N	X	X	X	X	X	N	N	N	N	N
Fibrosis; interstitial		.	2	.	.	.	.	.	.	.	.	.	.	.	.
PARATHYROID, RIGHT;		X	X	N	N	N	X	N	N	N	N	N	X	N	N	N
PEYERS PATCHES;		X	+	+	+	+	+	+	+	+	+	+	N	+	+
Mineralization		.	.	.	.	.	.	.	1	.	.	.	.	.	.
Inflammation, Granulomatous; follicular		.	.	.	.	.	.	.	.	.	.	.	.	.	.
germinal center; Increased Cellularity		.	3	2	2	2	3	2	2	2	3	3	3	.	3	3
PITUITARY GLAND;		N	X	N	N	N	N	N	N	N	N	N	N	N	N
pars distalis; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
pars intermedia; Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
SALIVARY GLANDS, MANDIBULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SALIVARY GLANDS, SUBLINGUAL;		N	N	N	N	N	N	N	N	N	N	N	X	N	N

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL NUMBER	1 9 6	1 9 7	1 9 8	1 9 9	2 0 0	2 0 1	2 0 2	2 0 3	2 0 4	2 0 5	2 0 6	2 0 7	2 0 8	2 1 0
SALIVARY GLANDS, PAROTIS;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN;		+	N	+	+	N	+	+	N	N	+	N	N	N	N
dermis; subcutis; Infiltration; mixed		2	.	2	1	.	3	1	.	.	3	.	.	.	.
SPINAL CORD;		+	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		2	.	.	.	.	.	.	.	.	.	.	.	.	.
SPLEEN;		+	+	+	+	+	+	+	+	+	+	+	N	N	+
Congestion		1	.	1	1	1	.	1	1	1	.	1	1	.	1
Hematopoiesis; increased		1	1	.	1	.	2	1	1	1	2	.	.	.	.
STOMACH, GLANDULAR;		+	+	+	+	+	+	+	N	+	+	+	+	N	+
Infiltration, Eosinophilic		1	.	2	1	1	1	1	.	2	1	2	1	.	2
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Dilation; glandular		.	1	.	.	.	.	.	.	.	.	.	.	.	1
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
chief cell; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
mucosa-associated lymphoid tissue; Hyperplasia		.	.	.	.	.	.	.	.	.	.	.	.	.	.
STOMACH, NONGLANDULAR;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
THYMUS;		+	+	+	N	+	+	+	N	+	+	+	N	N	N
Cyst		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage; acute		1	1	1	.	1	1	1	.	1	1	1	.	.	.
THYROID, LEFT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.
THYROID, RIGHT;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Cyst; keratinized		.	.	.	.	.	.	.	.	.	.	.	.	.	.

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

SEX: FEMALE	GROUP	7	7	7	7	7	7	7	7	7	7	7	7	7	7
	REMOVAL REASON	T	T	T	T	T	T	T	T	T	T	T	T	T	T
	ANIMAL	1	1	1	1	2	2	2	2	2	2	2	2	2	2
	NUMBER	9	9	9	9	0	0	0	0	0	0	0	0	0	1
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
TONGUE;		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage; acute		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Granuloma		.	.	.	.	.	.	.	.	.	.	.	.	.	.
TRACHEA;		N	N	N	N	N	N	N	N	N	N	N	+	N	N
Infiltration; lymphohistiocytic		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration; mixed		.	.	.	.	.	.	.	.	.	.	.	.	.	.
Infiltration, Lymphocytic		.	.	.	.	.	.	.	.	.	.	.	1	.	.
URINARY BLADDER;		N	N	N	N	+	N	N	N	N	N	N	N	N	N
Infiltration, Lymphocytic		.	.	.	.	1	.	.	.	.	.	.	.	.	.
UTERUS;		N	N	N	+	N	N	N	N	N	N	N	N	N	N
Dilation		.	.	.	2	.	.	.	.	.	.	.	.	.	.
VAGINA;		N	N	N	+	+	N	N	N	N	+	N	N	+	+	+
Keratinization; epithelial		.	.	.	2	1	.	.	.	.	2	.	.	1	1	2

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Tabulated Animal Data

Key Page

Group Code	Description
1	Group 1: Control
2	Group 2: 30 µg BNT162a1
3	Group 3: 10 µg BNT162a1
4	Group 4: 30 µg BNT162b1
5	Group 5: 100 µg BNT162b1
6	Group 6: 30 µg BNT162c1
7	Group 7: 100 µg BNT162b2

Removal Reason Code	Description
Term	Killed Terminal

Tissue Result Code	Description
N	Normal
.	Not Recorded
+	Tissue Observation Present
X	Not Examined

Grade Code	Description
.	not recorded
1	minimal
2	mild
3	moderate
4	marked
#	duplicate
P	present - no grade or classification

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	1	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : Inflammation; lymphohistiocytic, focal, mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	2	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE II : Inflammation; mixed, focal, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : acinar cell; Hyperplasia; focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	3	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	4	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Vacuolation; hepatocellular, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	5	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration; mixed, multifocal, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LUNGS WITH BRONCHI : macrophage; Pigmentation; brown, focal, minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : Infiltration; lymphohistiocytic, focal, minimal
TRACHEA : macrophage; Pigmentation; brown, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, CERVICAL - Not Present
MAMMARY GLANDS - Not Present
PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	6	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : myofiber; Degeneration; multifocal, minimal
NJECTION SITE I : muscle; Regeneration; multifocal, minimal
NJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Inflammation; purulent, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : In iltration, Lymphocytic; multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	7	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LUNGS WITH BRONCHI : Emphysematous (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : In iltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	8	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : Inflammation; lymphohistiocytic, focal, minimal
NJECTION SITE II : Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
THYROID, LEFT : Cyst; keratinized, single, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal
TONGUE : In iltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, CERVICAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	9	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

THYMUS : Discolouration; reddened (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, mild
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Infiltration, Eosinophilic; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	10	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : Inflammation; lymphohistiocytic, focal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Necrosis; focal, mild
LIVER : Infiltration, Neutrophilic; focal, mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : Cyst; single, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	11	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (4), (b) (6)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	12	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : Inflammation, Granulomatous; follicular, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars intermedia; Cyst; minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYROID, LEFT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	13	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	14	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TESTIS, LEFT : Spermatid Giant Cells; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	15	Group:	1 - Group 1	Sex:	Male
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

TESTIS, RIGHT : Enlarged (TGL) [TESTIS, RIGHT : Dilation; tubular, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TESTIS, LEFT : Dilation; tubular, mild
TESTIS, RIGHT : Dilation; tubular, moderate [TESTIS, RIGHT : Enlarged (G)]
TESTIS, RIGHT : Infiltration; lymphoplasmacytic, focal, moderate
TESTIS, RIGHT : Spermatocoele; single, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	16	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	17	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

NJECTION SITE I : Hemorrhage; focal, mild
NJECTION SITE I : Inflammation; mixed, focal, minimal
NJECTION SITE II : myofiber; Degeneration; focal, minimal
NJECTION SITE II : Inflammation; mixed, multifocal, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, mild
K DNEY, RIGHT : pelvis; Inflammation; purulent, mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild
TRACHEA : Infiltration; mixed, minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	18	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
ADRENAL GLAND, RIGHT : (Comment) artefacts
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : Inflammation; lymphohistiocytic, focal, minimal
NJECTION SITE I : Foreign Material; hair, focal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : acinar cell; Atrophy; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	19	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TONGUE : In iltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	20	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

NJECTION SITE I : Inflammation; granulomatous, focal, minimal
NJECTION SITE II : muscle; Regeneration; focal, minimal
NJECTION SITE II : Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	21	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EYE, LEFT : macrophage; Pigmentation; brown, focal, mild
HEART : (Comment) artefacts
NJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	22	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
NJECTION SITE II : Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYROID, LEFT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	23	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
SKELETAL MUSCLE : Infiltration, Lymphocytic; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, MESENTERIC - Not Present
SALIVARY GLANDS, SUBLINGUAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	24	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Hemorrhage; acute, mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	25	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, mild
NJECTION SITE I : Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : dermis; subcutis; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : Inflammation; lymphohistiocytic, focal, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	26	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
NTEST NE, RECTUM : Nematodiasis; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, LEFT : tubule; Cast; hyaline, multifocal, mild
K DNEY, LEFT : tubule; Degeneration; hyaline, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Ossification; focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	27	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	28	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Cyst; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, LEFT - Insufficient Tissue To Evaluate

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	29	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	30	Group:	1 - Group 1	Sex:	Female
		Dose:	Group 1: Control		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	31	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, mild
NTEST NE, RECTUM : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	31 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	32	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : inter- / perimuscular; Edema; mild
NJECTION SITE I : Hyperplasia; epidermal, mild
NJECTION SITE II : Hyperplasia; epidermal, focal, moderate
NJECTION SITE II : subcutis; Edema; focal, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; focal, mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; focal, mild
NJECTION SITE II : subcutis; Inflammation; mixed, focal, mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, focal, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	32 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	33	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

PROSTATE GLAND : Reduced In Size (TGL)

SEMINAL VESICLES : Reduced In Size (TGL)

ADRENAL GLAND, LEFT : Enlarged (TGL)

ADRENAL GLAND, RIGHT : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	33 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : Hyperplasia; epidermal, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : Ossification; focal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : pars distalis; Cyst; single, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	34	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, focal, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H) | NJECTION SITE I : subcutis; Inflammation; mixed, focal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, focal, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : Hyperkeratosis; epidermal, focal, moderate

NJECTION SITE I : Hyperplasia; epidermal, focal, moderate

NJECTION SITE II : myofiber; Degeneration; mild

NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate

NJECTION SITE II : subcutis; Edema; moderate

NJECTION SITE II : inter- / perimuscular; Edema; mild

NJECTION SITE II : myofiber; Necrosis; focal, minimal

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild

NJECTION SITE II : subcutis; Inflammation; mixed, moderate

NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, moderate

NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate

K DNEY, LEFT : Congestion; mild

K DNEY, RIGHT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	34 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, RIGHT : (Comment) incomplete

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	35	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : (Comment) artefacts
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration; mixed, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	35 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

AORTA ABDOMINALIS - Not Present
PEYERS PATCHES - Not Present
URINARY BLADDER - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	36	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : epidermis; Ulceration; multifocal, mild
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : (Comment) artefacts
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	36 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SALIVARY GLANDS, PAROTIS : Infiltration, Lymphocytic; multifocal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYROID, RIGHT : Cyst; keratinized, multiple, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PROSTATE GLAND - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	37	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]
NJECTION SITE I : Thickened (TGL) [NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild (H)]
NJECTION SITE II : Incrusted (TGL) [NJECTION SITE II : Scab; epidermal, focal, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : dermis; subcutis; Necrosis; multifocal, mild
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : Hyperplasia; epidermal, focal, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : Scab; epidermal, focal, mild [NJECTION SITE II : Incrusted (G)]
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : myofiber; Necrosis; traumatic, focal, minimal
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	37 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	38	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : epidermis; Ulceration; focal, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	39	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : muscle; Regeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, focal, moderate
NJECTION SITE II : Scab; epidermal, focal, mild
NJECTION SITE II : dermis; subcutis; Necrosis; focal, moderate
NJECTION SITE II : Ulceration; epidermal, focal, mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, RIGHT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	39 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; marked
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	40	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	40 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	41	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration; lymphohistiocytic, focal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE I : inter- / perimuscular; Mineralization; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Multinucleated Macrophages; multifocal, mild
NTEST NE, COLON : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration, Lymphocytic; multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	41 (Continued)	Group:	2 - Group 2	Sex:	Male

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	42	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE I : inter- / perimuscular; Mineralization; multifocal, mild
NJECTION SITE I : inter- / perimuscular; Multinucleated Macrophages; multifocal, mild
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : macrophage; alveolus; Infiltration; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SEMINAL VESICLES : Infiltration, Lymphocytic; focal, minimal
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	43	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	44	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : macrophage; Pigmentation; brown, focal, minimal
PITUITARY GLAND : pars distalis; Cyst; few, mild
PROSTATE GLAND : Infiltration, Lymphocytic; focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present
TESTIS, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	45	Group:	2 - Group 2	Sex:	Male
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : macrophage; Pigmentation; brown, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : (Comment) incomplete
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	46	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

CERVIX : Keratinization; epithelial, mild

HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	46 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : (Comment) artefacts
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	47	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : (Comment) artefacts
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Inflammation, Chronic; interstitial, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : Hemorrhage; acute, focal, mild
PITUITARY GLAND : pars distalis; Cyst; single, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	47 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	48	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Scab; epidermal, focal, mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, mild
SPLEEN : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	48 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

THYMUS : Hemorrhage; acute, multifocal, mild
THYROID, LEFT : Cyst; keratinized, single, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	49	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : epidermis; Ulceration; focal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : epidermis; Ulceration; focal, moderate [INJECTION SITE I : Incrusted (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	49 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	50	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

CERVIX : Keratinization; epithelial, mild

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : epidermis; Ulceration; focal, moderate

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

K DNEY, LEFT : Congestion; moderate

K DNEY, RIGHT : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	50 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, mild
THYROID, LEFT : Cyst; keratinized, single, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	51	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

UTERUS : Dilation (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration; lymphohistiocytic, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Scab; epidermal, focal, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, LEFT : tubule; Cast; hyaline, multifocal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	51 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : chief cell; Hyperplasia; mild
THYMUS : Hemorrhage; acute, multifocal, mild
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	52	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

K DNEY, LEFT : Congestion; mild

KIDNEY, LEFT : Mineralization; focal, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	52 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
K DNEY, RIGHT : Mineralization; focal, mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	53	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : epidermis; Ulceration; focal, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened (G)]

NJECTION SITE I : epidermis; Ulceration; focal, moderate [NJECTION SITE I : Incrusted : (Comment) skin (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	53 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Ossification; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	54	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	54 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PARATHYROID, LEFT : Fibrosis; interstitial, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	55	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, multifocal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G) | INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G) | NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	55 (Continued)	Group:	2 - Group 2	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, LEFT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	56	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYROID, RIGHT : Cyst; keratinized, multiple, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	57	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Pyelonephritis; minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	58	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
HARDERIAN GLAND, RIGHT : Inflammation, Chronic; focal, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	59	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	60	Group:	2 - Group 2	Sex:	Female
		Dose:	Group 2: 30 µg/BNT162a1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : dermis; subcutis; Fibrosis; multifocal, mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : (Comment) artefacts
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	61	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

HEART : Infiltration; lymphohistiocytic, focal, moderate

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]

NJECTION SITE I : epidermis; Ulceration; multifocal, moderate

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]

NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Indurated (G)]

NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild

K DNEY, LEFT : Congestion; moderate

K DNEY, RIGHT : Congestion; moderate

LIVER : Congestion; moderate

LIVER : Infiltration, Lymphocytic; multifocal, minimal

LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

LYMPH NODE, CERVICAL : Histocytosis; mild

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild

LYMPH NODE, ILIAC : Histocytosis; minimal

LYMPH NODE, ILIAC : Plasmacytosis; mild

LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	61 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	62	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; mild
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : Hemorrhage; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration; mixed, focal, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	62 (Continued)	Group:	3 - Group 3	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	63	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : subcutis; Hemorrhage; focal, mild

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened : (Comment) skin incrusted (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened : (Comment) skin incrusted (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : epidermis; Ulceration; focal, moderate

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	63 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened : (Comment) skin incrusted (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Thickened : (Comment) skin incrusted (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal
TRACHEA : Infiltration; lymphohistiocytic, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	64	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	64 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
K DNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	65	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Scab; epidermal, focal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	65 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present
SALIVARY GLANDS, PAROTIS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	66	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; minimal (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	66 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; multifocal, minimal
PEYERS PATCHES : Inflammation, Granulomatous; follicular, multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Cyst; single, mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	67	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	67 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	68	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	69	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; mild
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYRO D, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	70	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Inflammation, Chronic; focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : inter- / perimuscular; Edema; mild
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	70 (Continued)	Group:	3 - Group 3	Sex:	Male

Histopathology Observations [Correlation] (Continued):

TRACHEA : Infiltration; mixed, minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	71	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, mild
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	72	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : (Comment) artefacts
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; focal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	73	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; moderate
NTEST NE, RECTUM : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; focal, moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	74	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, mild
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : Infiltration; mixed, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TONGUE : Granuloma; hair, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	75	Group:	3 - Group 3	Sex:	Male
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; moderate
K DNEY, LEFT : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : tubule; Basophilia; multifocal, moderate
K DNEY, RIGHT : Inflammation, Chronic; interstitial, multifocal, moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : Hemorrhage; acute, focal, mild
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	76	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Inflammation, Chronic; focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Necrosis; multifocal, minimal
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
NERVE, SCIATIC : perineural; Inflammation; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	76 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; moderate
UTERUS : Dilation; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	77	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; mixed, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	78	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; mixed, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, RECTUM : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Inflammation, Chronic; interstitial, focal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	78 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	79	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

UTERUS : Dilation (TGL) [UTERUS : Dilation; mild (H)]

UTERUS : Filled With Liquid : (Comment) clear (TGL) [UTERUS : Dilation; mild (H)]

ADRENAL GLAND, LEFT : Enlarged (TGL) [ADRENAL GLAND, LEFT : Hypertrophy; cortical, mild (H)]

ADRENAL GLAND, RIGHT : Enlarged (TGL) [ADRENAL GLAND, RIGHT : Hypertrophy; cortical, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Hypertrophy; cortical, mild [ADRENAL GLAND, LEFT : Enlarged (G)]
ADRENAL GLAND, RIGHT : Hypertrophy; cortical, mild [ADRENAL GLAND, RIGHT : Enlarged (G)]
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : Mineralization; focal, mild
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	79 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : Vacuolation; multifocal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
TRACHEA : (Comment) artefacts
UTERUS : Dilation; mild [UTERUS : Filled With Liquid : (Comment) clear (G) | UTERUS : Dilation (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LACRIMAL GLAND, RIGHT - Not Present
PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	80	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, minimal
HEART : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	80 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

MAMMARY GLANDS : interstitium; Inflammation; mixed, multifocal, minimal
SPLEEN : Congestion; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	81	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	81 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : macrophage; Pigmentation; brown, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	82	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

UTERUS : Dilation (TGL)

UTERUS : Filled With Liquid : (Comment) clear (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : Infiltration, Lymphocytic; focal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	82 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Infiltration, Lymphocytic; focal, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	83	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

UTERUS : Dilation (TGL)

UTERUS : Filled With Liquid : (Comment) clear (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	83 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	84	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Enlarged (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : surrounding tissue; muscle; Infiltration; mixed, focal, mild
HARDERIAN GLAND, RIGHT : In iltration; mixed, multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	84 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	85	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; minimal (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration; mixed, multifocal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; minimal [INJECTION SITE I : Thickened (G)]
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	85 (Continued)	Group:	3 - Group 3	Sex:	Female

Histopathology Observations [Correlation] (Continued):

OPTIC NERVE, RIGHT : macrophage; Infiltration; foamy, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, LEFT : Cyst; keratinized, single, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	86	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : (Comment) artefacts
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : macrophage; Pigmentation; brown, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : pars intermedia; Cyst; minimal
SPLEEN : Congestion; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	87	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Erythrophagocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	88	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; lymphohistiocytic, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	89	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : Inflammation, Granulomatous; follicular, multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration, Lymphocytic; multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	90	Group:	3 - Group 3	Sex:	Female
		Dose:	Group 3: 10 µg/BNT162a1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Cyst; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
THYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	91	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Inflammation; mixed, marked (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Necrosis; focal, mild
LIVER : Infiltration, Neutrophilic; focal, mild
LIVER : Infiltration, Lymphocytic; focal, minimal
LIVER : Vacuolation; hepatocellular, focal, mild
LUNGS WITH BRONCHI : Ossification; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	91 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	92	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
ADRENAL GLAND, RIGHT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : perivascular; Inflammation; plasmacytic, multifocal, moderate
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
KIDNEY, LEFT : tubule; Basophilia; multifocal, minimal
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	92 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Erythrophagocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	93	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, RECTUM : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Infiltration, Eosinophilic; focal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	93 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

MAMMARY GLANDS - Not Present
OPTIC NERVE, RIGHT - Not Present
PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present
THYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	94	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; mild
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Inflammation; purulent, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	94 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	95	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration; mixed, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	95 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present
URINARY BLADDER - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	96	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	96 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	97	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration; mixed, multifocal, minimal
NJECTION SITE I : subcutis; Inflammation; mixed, mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, mild
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	97 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	98	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]
SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Mineralization; focal, minimal
K DNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	98 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration; mixed, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Infiltration, Lymphocytic; focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	99	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, marked (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LUNGS WITH BRONCHI : Infiltration; lymphohistiocytic, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	99 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	100	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

HEART : Infiltration; lymphohistiocytic, focal, minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : myofiber; Degeneration; minimal

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

NTEST NE, RECTUM : Infiltration, Eosinophilic; increased, mild

KIDNEY, LEFT : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	100 (Continued)	Group:	4 - Group 4	Sex:	Male

Histopathology Observations [Correlation] (Continued):

K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, focal, mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	101	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
TRACHEA : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	102	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Vacuolation; hepatocellular, multifocal, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; widespread, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	103	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

TESTIS, RIGHT : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Oligospermia; mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LIVER : Necrosis; focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
SPLEEN : Congestion; minimal
TESTIS, LEFT : Dilation; tubular, mild
TESTIS, RIGHT : Dilation; tubular, moderate
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	103 (Continued)	Group:	4 - Group 4	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	104	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : macrophage; alveolus; Infiltration; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	105	Group:	4 - Group 4	Sex:	Male
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, RECTUM : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : macrophage; Infiltration; foamy, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; focal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	106	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration; mixed, focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	106 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
UTERUS : Dilation; mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	107	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : subcutis; Edema; mild
NJECTION SITE I : intramuscular / interstitial; Edema; minimal
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	107 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	108	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated : (Comment) muscles (G) | NJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [NJECTION SITE I : Indurated : (Comment) muscles (G) | INJECTION SITE I : Thickened : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	108 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	109	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H)]
UTERUS : Dilation (TGL) [UTERUS : Dilation; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; mild
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
OPTIC NERVE, RIGHT : macrophage; Pigmentation; brown, focal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
UTERUS : Dilation; mild [UTERUS : Dilation (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	109 (Continued)	Group:	4 - Group 4	Sex:	Female

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	110	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	110 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	111	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, mild
HARDERIAN GLAND, LEFT : macrophage; Pigmentation; brown, focal, mild
HEART : (Comment) artefacts
HEART : Infiltration; mixed, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
NERVE, SCIATIC : perineural; Inflammation; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	111 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

PANCREAS : acinar cell; Atrophy; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	112	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hemorrhage; focal, moderate
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Cyst; tubular, single, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	112 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	113	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged : (Comment) right (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	114	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : (Comment) artefacts

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	114 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TONGUE : Hemorrhage; acute, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	115	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	02/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	02/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration; mixed, multifocal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	115 (Continued)	Group:	4 - Group 4	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

SALIVARY GLANDS, SUBLINGUAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	116	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PANCREAS : Infiltration, Lymphocytic; focal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	117	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
K DNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : (Comment) artefacts
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	118	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	119	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : (Comment) artefacts
ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : (Comment) artefacts
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, CECUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Inflammation, Granulomatous; follicular, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	120	Group:	4 - Group 4	Sex:	Female
		Dose:	Group 4: 30 µg/BNT162b1/animal		
Death Date:	23/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	23/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	121	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Enlarged (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

NJECTION SITE II : Enlarged (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
HARDERIAN GLAND, RIGHT : In iltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked [NJECTION SITE II : Enlarged (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	121 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : subcapsular; Infiltration, Neutrophilic; focal, minimal
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LIVER : kupffer cell; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
LYMPH NODE, RENAL : Histocytosis; mild
LYMPH NODE, RENAL : macrophage; Pigmentation; brown, focal, minimal
LYMPH NODE, RENAL : germinal center; Increased Cellularity; minimal
NERVE, SCIATIC : perineural; Inflammation; minimal
PANCREAS : Infiltration, Lymphocytic; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	122	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; mild
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : tubule; Cast; hyaline, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	122 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Infiltration, Eosinophilic; minimal
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : (Comment) artefacts
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SEMINAL VESICLES : surrounding tissue; fat; Infiltration; mixed, focal, moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	123	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, minimal (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL)

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE II : subcutis; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphocytic, focal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, minimal [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; mild [NJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NTEST NE, RECTUM : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	123 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node, subcutis, dermis
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	124	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL)
NJECTION SITE II : Thickened (TGL) [NJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked [NJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	124 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; marked
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : Infiltration, Eosinophilic; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	125	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	125 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Inflammation; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	126	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	126 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Inflammation, Chronic; interstitial, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	127	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

ADRENAL GLAND, LEFT : Enlarged (TGL)

ADRENAL GLAND, RIGHT : Enlarged (TGL)

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : subcutis; Edema; mild (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

EYE, RIGHT : (Comment) artefacts

NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal: 127 (Continued) Group: 5 - Group 5 Sex: Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; mild [NJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; focal, minimal
SKIN : subcutaneous; Infiltration; mixed, focal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	128	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : surrounding tissue; muscle; Infiltration; mixed, multifocal, mild
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	128 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	129	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : Inflammation; moderate (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) artefacts
HARDERIAN GLAND, RIGHT : Infiltration, Lymphocytic; focal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	129 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PROSTATE GLAND - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	130	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, minimal (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL)

ADRENAL GLAND, LEFT : Enlarged (TGL)

ADRENAL GLAND, RIGHT : Enlarged (TGL)

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, minimal [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [NJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	130 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Indurated : (Comment) muscle (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated : (Comment) muscle (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	131	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	132	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; minimal (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
NTEST NE, RECTUM : (Comment) artefacts
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : tubule; Cast; hyaline, focal, minimal
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	132 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	133	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	133 (Continued)	Group:	5 - Group 5	Sex:	Male

Histopathology Observations [Correlation] (Continued):

PROSTATE GLAND : Inflammation; purulent, focal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	134	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : intramuscular / interstitial; Fibrosis; minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, ILIAC : germinal center; Increased Cellularity; minimal [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

SALIVARY GLANDS, PAROTIS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	135	Group:	5 - Group 5	Sex:	Male
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; moderate (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BRA N, CEREBELLUM : (Comment) artefacts
BRA N, CEREBRUM : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	135 (Continued)	Group:	5 - Group 5	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	136	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Necrosis; focal, mild
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; minimal
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	136 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; focal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, LIAC - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	137	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal (H) | INJECTION SITE I : subcutis; Edema; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Degeneration; minimal
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal: 137 (Continued) Group: 5 - Group 5 Sex: Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration, Eosinophilic; minimal
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : Infiltration, Eosinophilic; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; lymphohistiocytic, focal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : Infiltration; mixed, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	138	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

NJECTION SITE II : Thickened (TGL) [NJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	138 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [NJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]

NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [NJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [NJECTION SITE II : Thickened (G) | INJECTION SITE II : Indurated : (Comment) muscles (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Thickened (G) | NJECTION SITE II : Indurated : (Comment) muscles (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G) | NJECTION SITE II : Indurated : (Comment) muscles (G)]
KIDNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PARATHYROID, LEFT : Fibrosis; interstitial, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	138 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	139	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, LIAC : Inflammation; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

NJECTION SITE II : Thickened (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; minimal (H) | NJECTION SITE II : subcutis; Edema; mild (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EYE, LEFT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; minimal
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; mild [NJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; minimal [NJECTION SITE II : Thickened (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	139 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	140	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H) | LYMPH NODE, LIAC : Inflammation; moderate (H)]

NJECTION SITE II : Thickened (TGL) [NJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BONE, STERNUM : surrounding tissue; muscle; Infiltration; mixed, focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	140 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; moderate [SPLEEN : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	141	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Inflammation; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]
SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, minimal
EYE, LEFT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	141 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

URINARY BLADDER - Insufficient Tissue To Evaluate

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	142	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

NERVE, SCIATIC : (Comment) left

NERVE, SCIATIC : Adhesion : (Comment) to injection site I (TGL) [NERVE, SCIATIC : perineural; Inflammation; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

NJECTION SITE II : Thickened (TGL) [NJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : subcutis; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	142 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Ossification; focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate [NERVE, SCIATIC : Adhesion : (Comment) to injection site I (G)]
SKIN : dermis; subcutis; Infiltration; mixed, mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYROID, LEFT : Cyst; keratinized, single, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	143	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; moderate
NJECTION SITE II : inter- / perimuscular; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	143 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, LEFT : Infiltration, Lymphocytic; focal, mild
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, focal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	144	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : Inflammation; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; marked
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	144 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OVIDUCT, LEFT - Not Present
PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	145	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; marked
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : macrophage; alveolus; Infiltration; foamy, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	145 (Continued)	Group:	5 - Group 5	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	146	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Infiltration; lymphohistiocytic, focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	147	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

UTERUS : Dilation (TGL) [UTERUS : Dilation; moderate (H)]
UTERUS : Filled With Liquid : (Comment) clear (TGL) [UTERUS : Dilation; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; multifocal, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; mild
K DNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : Mineralization; multifocal, mild
PEYERS PATCHES : Inflammation, Granulomatous; follicular, multifocal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
UTERUS : Dilation; moderate [UTERUS : Dilation (G) | UTERUS : Filled With Liquid : (Comment) clear (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	148	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Mineralization; focal, minimal
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	149	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; minimal (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OVIDUCT, RIGHT - Not Present
PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	150	Group:	5 - Group 5	Sex:	Female
		Dose:	Group 5: 100 µg/BNT162b1/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : macrophage; Pigmentation; brown, focal, mild
HARDERIAN GLAND, LEFT : Inflammation, Chronic; focal, mild
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Infiltration; mixed, focal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	151	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Necrosis; focal, minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	151 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa; Infiltration, Neutrophilic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	152	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : myofiber; Necrosis; focal, minimal
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscles (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	152 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, focal, minimal
LIVER : Infiltration; mixed, focal, minimal
LIVER : Necrosis; focal, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; focal, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

BONE, STERNUM - No Section

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	153	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	153 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Inflammation; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	154	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : subcutis; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; moderate
NJECTION SITE I : subcutis; Edema; marked [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, mild
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration; mixed, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	154 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	155	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL)
SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LUNGS WITH BRONCHI : Infiltration; lymphohistiocytic, focal, mild
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	156	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Inflammation; moderate (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	156 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : inter- / perimuscular; Edema; mild [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Inflammation; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Inflammation; purulent, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	157	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	157 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	158	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : Scab; epidermal, multifocal, mild (H) | NJECTION SITE I : epidermis; Ulceration; multifocal, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : epidermis; Ulceration; multifocal, mild [INJECTION SITE I : Incrusted (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	158 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Scab; epidermal, multifocal, mild [INJECTION SITE I : Incrusted (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	159	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, mild
K DNEY, RIGHT : tubule; Dilation; focal, mild
LIVER : Congestion; moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	159 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; lymphatic; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	160	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : In iltration; lymphohistiocytic, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	160 (Continued)	Group:	6 - Group 6	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	161	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration; mixed, multifocal, minimal
LIVER : Necrosis; focal, marked
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PITUITARY GLAND : (Comment) incomplete
PROSTATE GLAND : Inflammation; purulent, focal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	162	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	163	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	164	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, LEFT : (Comment) artefacts
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	165	Group:	6 - Group 6	Sex:	Male
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	166	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	166 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	167	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Inflammation; purulent, focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : epidermis; Ulceration; multifocal, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	167 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
THYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	168	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

SPLEEN : Enlarged (TGL)

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	168 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Cyst; focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	169	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
BRA N, CEREBRUM : (Comment) artefacts
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Inflammation; granulomatous, focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]

NJECTION SITE I : myofiber; Degeneration; moderate
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	169 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
THYROID, RIGHT : (Comment) artefacts
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	170	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; multifocal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	170 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars distalis; Cyst; few, minimal
SPLEEN : Congestion; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	171	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, LEFT : Inflammation; granulomatous, focal, mild
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	171 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, mild
SPLEEN : Congestion; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present
SALIVARY GLANDS, PAROTIS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	172	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : myofiber; Degeneration; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : myofiber; Degeneration; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EYE, LEFT : (Comment) artefacts
EYE, RIGHT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hemorrhage; focal, mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; moderate [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	172 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
OPTIC NERVE, RIGHT : Hemorrhage; acute, focal, mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
TRACHEA : Infiltration, Lymphocytic; focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OVARY, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	173	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Incrusted (TGL) [INJECTION SITE I : epidermis; Ulceration; focal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Inflammation; vascular, multifocal, moderate
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : epidermis; Ulceration; focal, moderate [NJECTION SITE I : Incrusted (G)]
NJECTION SITE I : myofiber; Degeneration; moderate
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	173 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
STOMACH, GLANDULAR : chief cell; Hyperplasia; multifocal, mild
THYROID, RIGHT : Cyst; keratinized, single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	174	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; marked (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; moderate
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Scab; epidermal, focal, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	174 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : (Comment) including lymph node
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	175	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	01/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	01/04/2020	Study Day (Week) of Death:	10 (2)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
EYE, RIGHT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : myofiber; Degeneration; moderate
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; minimal [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Indurated : (Comment) muscle (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
K DNEY, LEFT : Congestion; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	175 (Continued)	Group:	6 - Group 6	Sex:	Female

Histopathology Observations [Correlation] (Continued):

K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Erythrophagocytosis; minimal
LYMPH NODE, CERVICAL : macrophage; Pigmentation; brown, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
MAMMARY GLANDS : interstitium; Inflammation; mixed, focal, moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, minimal
THYMUS : Hemorrhage; acute, multifocal, mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	176	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, mild
CERVIX : Cyst; keratinized, moderate
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

NERVE, SCIATIC - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	177	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, COLON : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	178	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Infiltration, Lymphocytic; focal, minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, focal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	179	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration; mixed, focal, minimal
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
THYROID, RIGHT : Cyst; keratinized, single, minimal
TONGUE : Granuloma; single, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	180	Group:	6 - Group 6	Sex:	Female
		Dose:	Group 6: 30 µg/BNT162c1/animal		
Death Date:	22/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	22/04/2020	Study Day (Week) of Death:	31 (5)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	181	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, marked (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]
NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : subcutis; Fibrosis; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HARDERIAN GLAND, LEFT : Infiltration; lymphohistiocytic, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Fibrosis; mild [NJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	181 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : Dilation; glandular, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	182	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal: 182 (Continued) Group: 7 - Group 7 Sex: Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, LEFT : tubule; Cast; hyaline, focal, minimal
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; minimal
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	183	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; focal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : tubule; Cast; hyaline, multifocal, minimal
K DNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, mild
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	183 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars distalis; Cyst; few, minimal
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PANCREAS - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	184	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

NJECTION SITE I : Enlarged (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]
LYMPH NODE, RENAL : Enlarged (TGL) [LYMPH NODE, RENAL : Plasmacytosis; mild (H) | LYMPH NODE, RENAL : germinal center; Increased Cellularity; mild (H)]
NJECTION SITE II : Enlarged (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : subcutis; Edema; moderate (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : Hemorrhage; focal, mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE I : Thickened (G) | NJECTION SITE I : Enlarged (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]

NJECTION SITE I : myofiber; Degeneration; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal: 184 (Continued) Group: 7 - Group 7 Sex: Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Enlarged (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Thickened (G) | INJECTION SITE I : Enlarged (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Enlarged (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Enlarged (G)]
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
LYMPH NODE, RENAL : Histocytosis; minimal
LYMPH NODE, RENAL : Plasmacytosis; mild [LYMPH NODE, RENAL : Enlarged (G)]
LYMPH NODE, RENAL : germinal center; Increased Cellularity; mild [LYMPH NODE, RENAL : Enlarged (G)]
NERVE, SCIATIC : perineural; Inflammation; marked
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	185	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; focal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	185 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, focal, minimal
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PITUITARY GLAND : pars distalis; Cyst; few, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; mild
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	186	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : Necrosis; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	186 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : Plasmacytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : pars distalis; Cyst; few, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

OPTIC NERVE, RIGHT - Not Present
PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	187	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL)

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : subcutis; Edema; marked (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : (Comment) artefacts
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) incomplete
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked [NJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	187 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; minimal
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration; mixed, focal, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	188	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

NJECTION SITE II : Thickened (TGL) [NJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Vacuolation; cortical, mild
ADRENAL GLAND, RIGHT : (Comment) artefacts
ADRENAL GLAND, RIGHT : Vacuolation; cortical, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Thickened (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	188 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Thickened (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Thickened (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; multifocal, minimal
K DNEY, LEFT : Inflammation, Chronic; interstitial, focal, mild
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Mineralization; focal, minimal
LIVER : Congestion; moderate
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; moderate
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; focal, minimal
NERVE, SCIATIC : perineural; Inflammation; marked
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	189	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : Inflammation; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	189 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : Hemorrhage; focal, mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; moderate
KIDNEY, LEFT : tubule; Basophilia; focal, minimal
K DNEY, LEFT : Infiltration, Lymphocytic; multifocal, minimal
K DNEY, LEFT : Mineralization; multifocal, minimal
KIDNEY, RIGHT : Congestion; moderate
K DNEY, RIGHT : Mineralization; multifocal, minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : Necrosis; muscular, multifocal, minimal
SKIN : Infiltration, Neutrophilic; muscular, multifocal, mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : (Comment) artefacts
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	190	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : subcutis; Edema; minimal
NJECTION SITE II : intramuscular / interstitial; Edema; minimal
NJECTION SITE II : inter- / perimuscular; Edema; mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	190 (Continued)	Group:	7 - Group 7	Sex:	Male

Histopathology Observations [Correlation] (Continued):

LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SKELETAL MUSCLE : Infiltration; mixed, multifocal, minimal
SKELETAL MUSCLE : myofiber; Necrosis; multifocal, minimal
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	191	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
EYE, RIGHT : (Comment) artefacts
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : (Comment) artefacts
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	191 (Continued)	Group:	7 - Group 7	Sex:	Male

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	192	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HEART : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : Infiltration, Lymphocytic; focal, minimal
K DNEY, RIGHT : Congestion; moderate
KIDNEY, RIGHT : tubule; Basophilia; focal, minimal
K DNEY, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : (Comment) artefacts
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	193	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
HEART : Infiltration, Lymphocytic; focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	194	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BRA N, CEREBELLUM : (Comment) artefacts
BRA N, CEREBRUM : (Comment) artefacts
EPIDIDYMIS, LEFT : Infiltration, Lymphocytic; multifocal, minimal
EPIDIDYMIS, RIGHT : Infiltration, Lymphocytic; multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, multifocal, minimal
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
PROSTATE GLAND : Infiltration, Lymphocytic; multifocal, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	195	Group:	7 - Group 7	Sex:	Male
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LUNGS WITH BRONCHI : Hemorrhage; acute, multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PROSTATE GLAND : Infiltration, Lymphocytic; focal, moderate
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
STOMACH, GLANDULAR : mucosa-associated lymphoid tissue; Hyperplasia; mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	196	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; marked (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : epidermis; Ulceration; focal, mild
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; marked [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	196 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
SKIN : dermis; subcutis; Infiltration; mixed, mild
SPINAL CORD : Cyst; keratinized, single, mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
UTERUS : (Comment) incomplete
VAGINA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

CERVIX - Not Present
PARATHYROID, RIGHT - Not Present
PEYERS PATCHES - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	197	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Thickened (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

NJECTION SITE I : Adhesion : (Comment) to sciatic nerve and bone, muscle jellied (TGL) [INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal

NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Thickened (G) | NJECTION SITE I : Adhesion : (Comment) to sciatic nerve and bone, muscle jellied (G)]

NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Thickened (G)]

NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Thickened (G)]

NJECTION SITE I : myofiber; Degeneration; mild

NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Thickened (G)]

NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Thickened (G)]

NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Thickened (G)]

NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate

NJECTION SITE II : myofiber; Degeneration; mild

NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate

NJECTION SITE II : subcutis; Edema; moderate

NJECTION SITE II : intramuscular / interstitial; Edema; mild

NJECTION SITE II : inter- / perimuscular; Edema; moderate

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild

NJECTION SITE II : subcutis; Inflammation; mixed, moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	197 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
K DNEY, RIGHT : Mineralization; focal, minimal
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PARATHYROID, LEFT : Fibrosis; interstitial, mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present
PITUITARY GLAND - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	198	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; marked (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; moderate
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, multifocal, moderate
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, CECUM : Infiltration, Eosinophilic; increased, minimal
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	198 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; marked
OPTIC NERVE, LEFT : Hemorrhage; acute, focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : dermis; subcutis; Infiltration; mixed, focal, mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	199	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

UTERUS : Dilation (TGL) [UTERUS : Dilation; mild (H)]

UTERUS : Filled With Liquid : (Comment) clear (TGL) [UTERUS : Dilation; mild (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | INJECTION SITE II : subcutis; Edema; mild (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
CERVIX : Keratinization; epithelial, mild
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE II : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	199 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : subcutis; Edema; mild [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : dermis; subcutis; Infiltration; mixed, focal, minimal
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
UTERUS : Dilation; mild [UTERUS : Dilation (G) | UTERUS : Filled With Liquid : (Comment) clear (G)]
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	200	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, moderate
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; marked
NJECTION SITE II : myofiber; Necrosis; multifocal, minimal
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	200 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, focal, minimal
URINARY BLADDER : Infiltration, Lymphocytic; focal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	201	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE I : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Edema; marked (H) | NJECTION SITE I : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : subcutis; Edema; moderate (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H)]

NERVE, SCIATIC : (Comment) left

NERVE, SCIATIC : Adhesion : (Comment) to injection site I (TGL)

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE II : inter- / perimuscular; Edema; marked (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : dermis; epidermis; Inflammation; neutrophilic, focal, mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; marked [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Pustule; epidermal, focal, minimal
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; marked [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	201 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; mild
K DNEY, LEFT : Mineralization; multifocal, minimal
K DNEY, RIGHT : Congestion; mild
K DNEY, RIGHT : Mineralization; multifocal, minimal
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, focal, moderate
SPLEEN : Hematopoiesis; increased, mild
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present
PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	202	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; moderate (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, mild (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; minimal (H) | INJECTION SITE II : subcutis; Edema; minimal (H) | INJECTION SITE II : inter- / perimuscular; Edema; mild (H) | INJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : epidermis; Ulceration; focal, minimal
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE I : Scab; epidermal, focal, minimal
NJECTION SITE II : myofiber; Degeneration; minimal
NJECTION SITE II : subcutis; Edema; minimal [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; minimal [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	202 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, mild [NJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; mild
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SKIN : dermis; subcutis; Infiltration; mixed, minimal
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	203	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : subcutis; Inflammation; mixed, moderate
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; mild
NJECTION SITE I : intramuscular / interstitial; Edema; mild
NJECTION SITE I : inter- / perimuscular; Edema; moderate
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; minimal
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; minimal
NJECTION SITE II : intramuscular / interstitial; Edema; minimal
NJECTION SITE II : inter- / perimuscular; Edema; mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : subcutis; Inflammation; mixed, mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LIVER : Infiltration, Lymphocytic; multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LYMPH NODE, CERVICAL : Histocytosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	203 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal
LYMPH NODE, LIAC : Plasmacytosis; moderate
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : Mineralization; focal, minimal
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	204	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [INJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, minimal (H)]

NJECTION SITE II : Indurated : (Comment) muscle (TGL) [INJECTION SITE II : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate (H) | NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild (H) | NJECTION SITE II : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild (H) | NJECTION SITE II : intramuscular / interstitial; Edema; mild (H) | NJECTION SITE II : subcutis; Edema; moderate (H) | NJECTION SITE II : inter- / perimuscular; Edema; moderate (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : subcutis; Edema; moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Edema; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Edema; moderate [INJECTION SITE II : Indurated (G)]

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	204 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : subcutis; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild [INJECTION SITE II : Indurated (G)]
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate [INJECTION SITE II : Indurated (G)]
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : periportal; Vacuolation; hepatocellular, minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, ILIAC : Histocytosis; mild
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; mild
SPLEEN : Congestion; minimal
SPLEEN : Hematopoiesis; increased, minimal [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, focal, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	205	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	08/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	08/04/2020	Study Day (Week) of Death:	17 (3)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

NJECTION SITE I : Indurated (TGL) [NJECTION SITE I : subcutis; Inflammation; mixed, moderate (H) | INJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate (H) | INJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild (H) | INJECTION SITE I : inter- / perimuscular; Fibrosis; mild (H) | NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild (H) | INJECTION SITE I : subcutis; Edema; moderate (H) | NJECTION SITE I : inter- / perimuscular; Edema; moderate (H) | INJECTION SITE I : intramuscular / interstitial; Edema; mild (H)]

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; mild (H) | LYMPH NODE, LIAC : Plasmacytosis; moderate (H) | LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild (H)]

NERVE, SCIATIC : (Comment) left

NERVE, SCIATIC : Adhesion : (Comment) to injection site I (TGL)

SPLEEN : Enlarged (TGL) [SPLEEN : Hematopoiesis; increased, mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

BONE, OS FEMORIS WITH JOINT : surrounding tissue; Inflammation; mixed, focal, mild
BONE MARROW, OS FEMORIS WITH JOINT : Increased Cellularity; minimal
HARDERIAN GLAND, RIGHT : Infiltration; mixed, multifocal, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : subcutis; Inflammation; mixed, moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Inflammation; mixed, mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Inflammation; mixed, moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : myofiber; Degeneration; mild
NJECTION SITE I : subcutis; Edema; moderate [INJECTION SITE I : Indurated (G)]
NJECTION SITE I : intramuscular / interstitial; Edema; mild [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : inter- / perimuscular; Edema; moderate [NJECTION SITE I : Indurated (G)]
NJECTION SITE I : Hyperplasia; epidermal, widespread, moderate
NJECTION SITE II : myofiber; Degeneration; mild
NJECTION SITE II : Hyperplasia; epidermal, widespread, mild
NJECTION SITE II : subcutis; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Edema; mild
NJECTION SITE II : inter- / perimuscular; Edema; marked
NJECTION SITE II : intramuscular / interstitial; Fibrosis; mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	205 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

NJECTION SITE II : subcutis; Inflammation; mixed, moderate
NJECTION SITE II : intramuscular / interstitial; Inflammation; mixed, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; mixed, moderate
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Hematopoiesis; extramedullary, multifocal, minimal
LIVER : periportal; Vacuolation; hepatocellular, mild
LUNGS WITH BRONCHI : Infiltration; mixed, focal, mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Inflammation; minimal
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; moderate
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
NERVE, SCIATIC : perineural; Inflammation; moderate
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SKIN : dermis; subcutis; Infiltration; mixed, focal, moderate
SPLEEN : Hematopoiesis; increased, mild [SPLEEN : Enlarged (G)]
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
THYMUS : Hemorrhage; acute, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, LEFT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	206	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

HARDERIAN GLAND, LEFT : Infiltration, Lymphocytic; focal, mild
HARDERIAN GLAND, RIGHT : Infiltration; mixed, focal, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NTEST NE, COLON : Infiltration, Eosinophilic; increased, minimal
NTEST NE, RECTUM : In iltration, Eosinophilic; increased, minimal
K DNEY, LEFT : Congestion; mild
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : (Comment) artefacts
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal
LYMPH NODE, ILIAC : Plasmacytosis; mild
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild
LYMPH NODE, LIAC : germinal center; Increased Cellularity; moderate
LYMPH NODE, MESENTERIC : Histocytosis; minimal
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild
THYMUS : Hemorrhage; acute, multifocal, minimal

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	206 (Continued)	Group:	7 - Group 7	Sex:	Female

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	207	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; minimal (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
K DNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, ILIAC : Histocytosis; minimal [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; minimal
TRACHEA : (Comment) artefacts

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

PARATHYROID, RIGHT - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	208	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

No observations found

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

CERVIX : Keratinization; epithelial, minimal
K DNEY, LEFT : Congestion; moderate
K DNEY, LEFT : tubule; Cast; hyaline, focal, minimal
K DNEY, RIGHT : Congestion; mild
LIVER : Congestion; mild
LIVER : Infiltration; mixed, multifocal, mild
LUNGS WITH BRONCHI : macrophage; Pigmentation; brown, multifocal, minimal
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : macrophage; Pigmentation; mild
TRACHEA : Infiltration, Lymphocytic; focal, minimal
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

LYMPH NODE, CERVICAL - Not Present
LYMPH NODE, LIAC - Not Present
SALIVARY GLANDS, SUBLINGUAL - Not Present

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	209	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, LIAC : Enlarged (TGL) [LYMPH NODE, LIAC : Histocytosis; minimal (H) | LYMPH NODE, ILIAC : Plasmacytosis; minimal (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, moderate (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, LEFT : Dilation; vascular, minimal
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE II : inter- / perimuscular; Fibrosis; mild
NJECTION SITE II : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; mild
LYMPH NODE, CERVICAL : Histocytosis; mild
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; minimal [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : Plasmacytosis; minimal [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, moderate [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
LYMPH NODE, MESENTERIC : germinal center; Increased Cellularity; mild
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
PITUITARY GLAND : (Comment) incomplete
VAGINA : Keratinization; epithelial, minimal

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	210	Group:	7 - Group 7	Sex:	Female
		Dose:	Group 7: 100 µg/BNT162b2/animal		
Death Date:	29/04/2020	Removal Reason:	Killed Terminal		
Necropsy Date:	29/04/2020	Study Day (Week) of Death:	38 (6)		
		Histo Recorder:	(b) (6), (b) (4)		

Gross Pathology Animal Details:

No animal details found

Gross Pathology Observations [Correlation]:

LYMPH NODE, ILIAC : Enlarged (TGL) [LYMPH NODE, ILIAC : Histocytosis; mild (H) | LYMPH NODE, ILIAC : Plasmacytosis; mild (H) | LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild (H) | LYMPH NODE, ILIAC : germinal center; Increased Cellularity; mild (H)]

Gross Pathology - The following Tissues were Not Examined:

None

Gross Pathology - The following Protocol Required Tissues were Not Processed:

None

Histopathology Animal Details:

No animal details found

Histopathology Observations [Correlation]:

ADRENAL GLAND, RIGHT : Dilation; vascular, minimal
CERVIX : Keratinization; epithelial, mild
NJECTION SITE I : intramuscular / interstitial; Fibrosis; multifocal, minimal
NJECTION SITE I : inter- / perimuscular; Fibrosis; mild
NJECTION SITE I : intramuscular / interstitial; Inflammation; lymphohistiocytic, multifocal, mild
NJECTION SITE I : inter- / perimuscular; Inflammation; lymphohistiocytic, mild
NJECTION SITE II : inter- / perimuscular; Fibrosis; minimal
NJECTION SITE II : inter- / perimuscular; Inflammation; lymphohistiocytic, minimal
NTEST NE, RECTUM : (Comment) artefacts
NTEST NE, RECTUM : mucosa-associated lymphoid tissue; Hyperplasia; mild
K DNEY, LEFT : Congestion; moderate
KIDNEY, RIGHT : Congestion; moderate
LIVER : Congestion; moderate
LUNGS WITH BRONCHI : bronchial-associated lymphoid tissue; Hyperplasia; minimal
LUNGS WITH BRONCHI : perivascular; Infiltration, Eosinophilic; multifocal, minimal
LYMPH NODE, CERVICAL : Histocytosis; minimal
LYMPH NODE, CERVICAL : germinal center; Increased Cellularity; mild
LYMPH NODE, LIAC : Histocytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, ILIAC : Plasmacytosis; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, LIAC : Infiltration; macrophage, multifocal, mild [LYMPH NODE, LIAC : Enlarged (G)]
LYMPH NODE, LIAC : germinal center; Increased Cellularity; mild [LYMPH NODE, ILIAC : Enlarged (G)]
LYMPH NODE, MESENTERIC : Histocytosis; mild
SKELETAL MUSCLE : Infiltration, Lymphocytic; focal, minimal
NERVE, SCIATIC : perineural; Inflammation; minimal
PEYERS PATCHES : germinal center; Increased Cellularity; moderate
SPLEEN : Congestion; minimal
STOMACH, GLANDULAR : Infiltration, Eosinophilic; mild

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Animal:	210 (Continued)	Group:	7 - Group 7	Sex:	Female

Histopathology Observations [Correlation] (Continued):

STOMACH, GLANDULAR : Dilation; glandular, multifocal, minimal
VAGINA : Keratinization; epithelial, mild

Any remaining protocol required tissues, which have been examined, have no visible lesions

Histopathology - The following Tissues were Not Examined:

None

Histopathology - The following Protocol Required Tissues were Not Processed:

None

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(b) (4) Study No.: 38166 Repeat-Dose Toxicity Study

Individual Animal Data

Key Page

Codes

(TGL) = Trackable Gross Lesion, (MPF) = Major Pathological Finding, (?) = Questionable, (E) = Excluded,
(C) = Clinical Observation, (M) = Mass, (G) = Gross Pathology, (H) = Histopathology

Report Request Items

Animals Included: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210

Groups: All
Observation Type: Gross and Histo
Tissues: All
Removal Reasons: All

Group Information

Short Name	Long Name	Type
1	Group 1	Control
2	Group 2	Dose
3	Group 3	Dose
4	Group 4	Dose
5	Group 5	Dose
6	Group 6	Dose
7	Group 7	Dose

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7. APPENDICES

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APPENDIX 1

Certificate of Analysis

POLYMUN SCIENTIFIC
Immunbiologische Forschung GmbH

Donaustraße 99
A-3400 Klosterneuburg, Austria
Tel.: +43-2243-25060-300
Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBL063.3 LNP
Lot: CoVVAC/090320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

(b) (6)

Date: 26.03.2020

Date: 26.03.20

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POLYMUN SCIENTIFIC
Immunbiologische Forschung GmbH

Donaustraße 99
A-3400 Klosterneuburg, Austria
Tel.: +43-2243-25060-300
Fax: +43-2243-25060-399
E-Mail: office@polymun.com
http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBL063.1 LNP
Lot: CoVVAC/110320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

(b) (6)

Date: 26.03.2020

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Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBP020.3 LNP
Lot: CoVVAC/100320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

(b) (6)

Date: 26.03.2020

Date: 26.03.2020

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Non-GMP CoA

Material not for human use
Version 3

Product: **CoVVAC**
Batch: RBP020.1LNP
Lot: CoVVAC/160320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

(b) (6)

Date: 26.03.2020

Date: 26.03.2020

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POLYMUN SCIENTIFIC
Immunbiologische Forschung GmbH

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http://www.polymun.com

Non-GMP CoA

Material not for human use
Version 2

Product: **CoVVAC**
Batch: RBS004.3 LNP
Lot: CoVVAC/130320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

(b) (6)

Date: 26.03.2020

Date: 26.03.2020

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APPENDIX 2

Composition of the Diet; Limitation for Contaminants in the Diet, Drinking Water and Bedding Material

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ABBREVIATIONS

%	per cent
Bq	becquerel
IU	international unit
kg	kilogram
L	litre
mg	milligram
MJ	megajoule
ppb	parts per billion
µg	microgram

Composition of the diet

Standard Diet for Rats and Mice
ssniff® V1534 R/M-H, maintenance diet, pellets 10 mm
ssniff® V1535 R/M-H, maintenance diet, pellets 15 mm

(ssniff Spezialdiäten GmbH, 59494 Soest, Germany)

Ingredients
(average content in the diet %)

Crude protein	19.0
Crude fat	3.3
Crude fibres	5.0
Crude ash	6.4
N-free extracts	54.6
Starch	35.9
Sugar	5.4

Metabolizable Energy (MJ/kg)

Gross energy	16.2
Metabolizable energy	13.5

Amino Acids
(average content in the diet %)

Lysine	1.00
Methionine	0.33
Cystine	0.35
Met + Cys	0.68
Threonine	0.71
Tryptophan	0.25
Arginine	1.19
Histidine	0.48
Valine	0.90
Isoleucine	0.79
Leucine	1.39
Phenylalanine	0.88
Phe + Tyr	1.49
Glycine	0.88
Glutamic acid	4.10
Aspartic acid	1.79
Proline	1.29
Serine	0.99
Alanine	0.82

Minerals
(average content in the diet %)

Calcium	1.00
Phosphorus	0.70
Sodium	0.24
Magnesium	0.22
Potassium	0.92

Trace Elements
(average content diet in mg per 1000 g)

Iron	189
Manganese	68
Zinc	91
Copper	15
Iodine	2.1
Selenium	0.3

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Vitamins (additive per 1 000 g of diet)	
Vitamin A	15000 IU
Vitamin D3	1100 IU
Vitamin E	110 mg
Vitamin K (as MNB)	7 mg
Thiamine (B1)	18 mg
Riboflavin (B2)	22 mg
Pyridoxine (B 6)	21 mg
Cobalamin (B12)	100 µg
Nicotinic acid	115 mg
Pantothenic acid	40 mg
Folic acid	7 mg
Biotin	510 µg
Choline	1370 mg

Fatty Acids	[%]
C 12:0	-
C 14:0	0.01
C 16:0	0.45
C 18:0	0.09
C 20:0	0.01
C 16:1	0.01
C 18:1	0.62
C 18:2	1.76
C 18:3	0.23

Limitation for contaminants in the diet (ppb)

	min.	max.
Aflatoxin (B_1, B_2, G_1, G_2), total		5
Lindane		10
Heptachlor		10
Malathion		1000
DDT (Total)		50
Dieldrin		10
Cadmium		400
Arsenic		1000
Lead		1500
Mercury		100
Selenium	100	600
PCB		50

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Limitation for contaminants in the drinking water [mg/L]

		max.
Iron		0.200
Manganese		0.050
Ammonium		0.50
Chloride		250
Arsenic		0.010
Lead		0.010
Cadmium		0.0030
Chromium		0.050
Cyanide		0.050
Fluoride		1.5
Nickel		0.020
Nitrite		0.50
Nitrate		50
Mercury		0.0010
Vinylchloride		0.00050
Acrylamide		0.00010
Benzene		0.0010
Boron		1.0
Bromate		0.010
Selenium		0.010
Antimony		0.0050
Copper		2.0
Aluminium		0.200
Sodium		200
Sulphate		250
Uranium		0.010
Polycyclic aromatic hydrocarbons		
- Benzo-(b)-fluoroanthene		
- Benzo-(k)-fluoroanthene		
- Benzo-(ghi)-perylene		
- Indeno-(1,2,3-cd)-pyrene	total	0.00010
- Benzo-(a)-pyrene		0.000010
Chlorinated organic compounds		
Trihalogenemethane including Trichloromethane, Bromodichloromethane, Dibromochloromethane and Tribromomethane	total	0.050
- 1,2-Dichloroethane		0.0030
- Tetrachloroethene and Trichloroethene		0.010
- Epichlorohydrine		0.00010
Organic chemical compounds used as pesticides and biocides including their toxic metabolites except for		maximum of 0.00010/substance
- Aldrin		0.000030
- Dieldrin		0.000030
- Heptachlor		0.000030
- Heptachloroepoxide		0.000030
	maximum total of	0.00050
Tritium [Bq/L]		100
pH		between 6.5 and 9.5

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Limitation for contaminants in the bedding material [mg/kg]

	max.
Aflatoxin (B_1)	0.01
Chlordane	0.02
Endrine	0.01
Fluorine	150.00
Lindane	0.10
Heptachlor and epoxide	0.01
DDT, DDE, DDD	0.05
Dieldrin and aldrin	0.01
Arsenic	1.00
Lead	2.50
Mercury	0.10
Nitrite (Na-Nitrite)	15.00
HCB	0.01

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APPENDIX 3

GLP Certificate of the Test Facility (b) (4)

(b) (4), (b) (6)

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A P P E N D I X 4

Analytical report:

'Immunogenicity Assessment of BNT162a1, BNT162b1, BNT162b2 and BNT162c1 in Rat Serum after Repeated Intramuscular Administration'

(No. R-20-0104, provided by BioNtech SE, Germany)

BioNTech SE
An der Goldgrube 12
55131 Mainz, Germany
Phone: +49 (0)6131 9084-0
Telefax: +49 (0)6131 9084-390

R&D STUDY REPORT No. R-20-0104

IMMUNOGENICITY ASSESSMENT OF BNT162a1, BNT162b1, BNT162b2 AND BNT162c1 IN RAT SERUM AFTER REPEATED INTRAMUSCULAR ADMINISTRATION

Version 01
Date: 25JUN2020

Reported (b) (6)

Test item: serum of rats administered with BNT162a1, BNT162b1, BNT162b2, and BNT162c1
Key words: Coronavirus, COVID-19, ATM material, rat, immunogenicity

This R&D report consists of 33 pages.

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LIST OF ABBREVIATIONS

ATM	Animal trial material
COVID-19	Coronavirus disease 2019
ELISA	Enzyme-linked immunosorbent assay
HR	Heptad repeats
LNP	Lipid nanoparticle
(b) (4)	
modRNA	Nucleoside-modified mRNA
nAb	Neutralizing antibody
No	Number
PBS	Phosphate-buffered saline
pVNT	Pseudovirus-based neutralization test
RBD	Receptor binding domain
RNA	Ribonucleic acid
S protein	Spike protein
S1	Subdomain 1 of the S protein
S2	Subdomain 2 of the S protein
saRNA	Self-amplifying mRNA
SARS	Severe acute respiratory syndrome
SARS-CoV-2	Severe acute respiratory syndrome-Coronavirus-2
uRNA	Uridine-containing mRNA

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RESPONSIBILITIES

Person responsible for the study:	(b) (6) Development; BioNTech SE	23 Jun 2020 Date
Author:	(b) (6) BioNTech RNA Pharmaceuticals GmbH	18 Jun 2020 Date
Reviewer:	(b) (6) unit; BioNTech RNA Pharmaceuticals GmbH	19 JUN 2020 Date
QA representative:	(b) (6) BioNTech SE	25.06.2020 Date

Meaning of the signatures:

Person responsible for the study: I am responsible for the content of the R&D report and confirm that it represents an accurate record of the results. This study was performed according to the SOPs and methods as well as the rules and regulations described in the report.

Author: I am the author of this document.

Reviewer: I reviewed the R&D report and confirm that this document complies with the scientific and technical standards and requirements.

QA representative: I confirm that this document complies with the relevant quality assurance requirements.

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1 SUMMARY

BioNTech is developing RNA-based vaccines designed to protect against the novel coronavirus disease that emerged in 2019 (COVID-19). The project involves testing three RNA platforms which are under development at BioNTech with domains of the surface or spike protein (S protein) of the novel Coronavirus (SARS-CoV-2) as the viral antigen.

In the present accessory study to the GLP-compliant repeat-dose toxicity study in rats (b) (4) Study No. 38166), the immunogenicity of the administered SARS-CoV-2-S protein targeted RNA vaccines BNT162a1, BNT162b1, BNT162b2, and BNT162c1 was investigated. Serum samples were collected from (i) the treated main study animals at day 10 (BNT162c1) or at day 17 after first immunization (BNT162a1, BNT162b1, and BNT162b2) as well as (ii) the treated recovery cohorts at day 31 (BNT162c1) or at day 38 (BNT162a1, BNT162b1, and BNT162b2). The elicited antibody immune responses were analyzed by S1 domain and RBD sub-domain specific ELISA as well as VSV/SARS-CoV-2-S-based pseudovirus neutralization assay (pVNT).

The recorded data demonstrates that all BNT162 vaccine candidates elicited a SARS-CoV-2-S protein specific antibody response directed against the S1 domain and the RBD sub-domain. The antibody response induced by the BNT162c1 vaccine was low in extent and did not confer neutralization activity in most animals. The development of the BNT162c1 candidate was discontinued. For BNT162a1, BNT162b1 and BNT162b2 vaccines, antibody responses detected via ELISA increased over time and directly translated into neutralizing activity as seen in the VSV/SARS-CoV-2-S pseudovirus neutralization test. For those vaccine candidates, sera from animals with higher antigen-specific antibody titers also displayed more pronounced virus neutralization effect and, in case of modRNA based vaccines, BNT162b1 and BNT162b2, exceeded the upper limit of quantification of the assay.

(b) (6)

25 JUN 2020
Date

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2 GENERAL INFORMATION

2.1 Sponsor and Test Facilities

Sponsor

BioNTech RNA Pharmaceuticals GmbH
An der Goldgrube 12
55131 Mainz
Germany

Test Facility

BioNTech SE
An der Goldgrube 12
55131 Mainz
Germany

2.2 Participating Personnel

Responsible person: (as defined in SOP-100-024)	(b) (6)
Author:	
Experimenter:	
Experimenter:	
Experimenter:	

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2.3 Study Dates

Start of experiments: 07 APR 2020

Completion of experiments: 07 MAY 2020

2.4 Guidelines and Regulations

All experiments are executed in accordance with the existing standard operating procedures and described processes from BioNTech SE. Applicable documents are listed below.

- SOP-010-045 Brutschrank HERAcell 150i
- SOP-010-047 Zentrifuge Eppendorf 5810/5810R
- SOP-010-051 Tiefkühlschränke -80 °C
- SOP-010-058 Sicherheitswerkbank Klasse II
- SOP-010-086 Zentrifuge Thermo Scientific Heraeus Pico und Fresco 17
- SOP-020-009 Ansetzen von Medien und Zusätzen für die Zellkultur
- SOP-030-041 Auftauen von Zellen
- SOP-030-112 Durchführung eines virusprotein-spezifischen ELISA
- SOP-090-013 Biological safety in laboratories
- SOP-110-022 Entsorgung von Biostoffabfällen

2.5 Changes and Deviations

Not applicable. There is no formal R&D plan available.

2.6 Documentation and Archive

Study plans and reports are stored and archived according to SOP-100-003 Archiving of Paper-Based Documents.

Raw data and evaluated data are saved at:

- P:\BioNTechRNA\RN9391R00_CoV-VAC\04_Preclinic\02_Toxicology\Repeat-dose Toxicity\(b) (4) Studie 38166

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3 INTRODUCTION

3.1 Background

In December 2019, an outbreak of pneumonia of unknown cause in Wuhan, Hubei province in China started. The disease spread rapidly and in January 2020, the agent was identified. By June 9th 2020, infection with the novel Coronavirus (SARS-CoV-2) was confirmed in approximately 7,000,000 people with more than 400,000 casualties[1]. A vaccine is urgently needed and BioNTech decided to develop a rapid vaccine project based on the surface or spike protein (S protein) of the virus as the viral antigen. The S protein is a trimer and during viral egress, the precursor protein is cleaved into S1 and S2 subunits (Figure 1). While the S1 domain recognizes the host receptor, the S2 domain is essential for the membrane fusion of the viral envelope and the endosomal membrane. To initiate membrane fusion, the S2 domain undergoes a conformational change within the central helix domain.

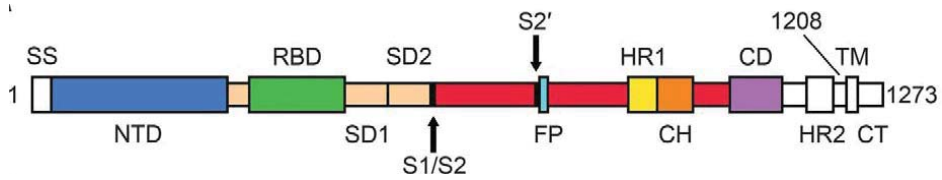


Figure 1: Schematic overview of the protein organization of the SARS-CoV-2 S protein

The sequence within the S1 subunit consists of the signal sequence (SS) and the receptor binding domain (RBD) which is the key subunit within the S protein which is relevant for binding to the human cellular receptor ACE2. The S2 subunit contains the S2 protease cleavage site (S2') followed by a fusion peptide (FP) for membrane fusion, heptad repeats (HR1 and HR2) with a central helix (CH) domain, the transmembrane domain (TM) and a cytoplasmic tail (CT); source: modified from (Wrapp et al. 2020).

Based on these features, the S protein is the prime target for vaccine development with a vaccine potentially eliciting neutralizing antibodies (nAb) that bind dominantly to the receptor-binding domain (RBD) of the S protein. Vaccine candidates selected for nonclinical testing include the following vaccine antigens:

- A secreted variant of the RBD of the SARS CoV-2 S-protein (vaccine candidate is called V5) (Kirchdoerfer et al. 2018)
- Membrane-tethered full-length S protein with two point mutations within the central helix domain. Mutation of the two amino acids to proline, (KV286-287PP) retains the S protein in an antigenically optimal prefusion conformation (vaccine candidate is called V8/V9 depending on the codon optimization used in the RNA) (Wrapp et al. 2020, Pallesen et al. 2017)

[1] Coronavirus disease (COVID-2019) situation report 141, World Health Organization; https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

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The development of *in vitro* transcribed RNA as an active platform for the use in infectious disease vaccines is based on the extensive knowledge of the company in RNA technology, which has been gained over the last decade. The core innovation is based on *in vivo* delivery of a pharmacologically optimized, antigen-coding RNA vaccine to induce robust nAbs and concomitant T-cell responses to achieve protective immunization with minimal vaccine doses (Vogel at al. 2017, Moyo et al. 2018, Pardi et al. 2017).

At BioNTech, there are three different RNA platforms under development, namely non-modified uridine-containing mRNA (uRNA), nucleoside-modified mRNA (modRNA) and self-amplifying RNA (saRNA). It is unknown today which RNA vaccine platform performs best in terms of activation and duration of a potent immune response. Therefore, BioNTech has developed a project plan evaluating the immune response of SARS-Co-V-2 vaccines based on all three platforms. The three vaccine platforms are currently tested for each antigen construct in non-clinical mouse studies to dissect the induced immunogenicity. Moreover, a GLP-compliant repeat-dose toxicity study was conducted to characterize the safety profile of each RNA platform and to assess to which extent any observed side effect is specific to the RNA platform, the vaccine dose and/or the encoded antigen. This report covers an accessory study to the REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS (b) (4) Study No. 38166) assessing the vaccine-induced immunogenicity seen in rats.

3.2 Objectives

The objective of this accessory study to the GLP-compliant repeat-dose toxicity study in rats ((b) (4) Study No. 38166) was to obtain information on the immunogenicity of the administered SARS-CoV-2-S protein targeted RNA vaccines BNT162a1, BNT162b1, BNT162b2 and BNT162c1 in the rats. The elicited antibody immune response directed against the S1 domain and the RBD sub-domain was analyzed by enzyme-linked immunosorbent assay (ELISA), and the neutralizing capacity of antibodies assessed via pseudovirus neutralization test (pVNT).

3.3 Study Design

In order to obtain information on the SARS-CoV-2-S specific antibody responses induced in the GLP-compliant repeat-dose toxicity study in rats ((b) (4) Study No. 38166), serum samples were collected from the treated main study animals at day 10 (BNT162c1) or at day 17 after first immunization (BNT162a1, BNT162b1, and BNT162b2) as well as from the treated recovery cohorts at day 31 (BNT162c1) or at day 38 (BNT162a1, BNT162b1, and BNT162b2). The corresponding study design of the *in vivo* study is summarized in Table 1. The elicited antibody immune response was analyzed by S1 domain and RBD sub-domain specific ELISA and VSV/SARS-CoV-2-S-based pVNT.

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Table 1: Study design of the GLP-compliant repeat-dose toxicity study (b) (4) Study No. 38166)

Test Items	• BNT162a1 (uRNA-LNP, RBD of the SARS-CoV-2 S protein) • BNT162b1 (modRNA-LNP, RBD of the SARS-CoV-2 S protein) • BNT162b2 (modRNA-LNP, mutated full-length S protein of the SARS-CoV-2 S protein) • BNT162c1 (saRNA-LNP, RBD of the SARS-CoV-2 S protein)	
Species(age)	Wistar Han rat (10-14 weeks)	
Administrations	Three (BNT162a1, BNT162b1 and BNT162b2) or two (BNT162c1) administrations on day 1, 8 and (if applicable) 15 followed by a 3-week recovery period	
Route	Intramuscular into the *M. biceps femoris*	
Dose groups	**Test Item**	**Dose level**
1	Control = Buffer	/
2	**BNT162a1** (uRNA RBD)	30 µg
3		10 µg
4	**BNT162b1** (modRNA RBD)	30 µg
5		100 µg
6	**BNT162c1** (saRNA RBD)	30 µg
7	**BNT162b2** (modRNA mutated full-length S protein)	100 µg
Satellite group (SA1)	SA1: for cytokine response analysis	3/sex/group
Group size	Group 1–7	10 (+ 5 recovery)/sex/group

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4 MATERIALS AND METHODS

4.1 Test Item

Table 2: Test serum derived from the GLP-compliant repeat-dose toxicity study (Study No. 38166).

Rat serum	Treatment and dose level	Time-point of serum generation
Group 2 (main study) (animals 31-40, 46-55)	30 µg/animal BNT162a1	Day 17
Group 2 (recovery cohort) (animals 41-45, 56-60)		Day 38
Group 3 (main study) (animals 61-70, 76-85)	10 µg/animal BNT162a1	Day 17
Group 3 (recovery cohort) (animals 71-75, 86-90)		Day 38
Group 4 (main study) (animals 91-100, 106-115)	30 µg/animal BNT162b1	Day 17
Group 4 (recovery cohort) (animals 101-105, 116-120)		Day 38
Group 5 (main study) (animals 121-130, 136-145)	100 µg/animal BNT162b1	Day 17
Group 5 (recovery cohort (animals 131-135, 146-150)		Day 38
Group 6 (main study) (animals 151-160, 166-175)	30 µg/animal BNT162c1	Day 10
Group 6 (recovery cohort) (animals 161-165, 176-180)		Day 31
Group 7 (main study) (animals 181-190, 196-205)	100 µg/animal BNT162b2	Day 17
Group 7 (recovery cohort) (animals 191-195, 206-210)		Day 38

4.2 Control Item

Table 3: Control serum derived from the GLP-compliant repeat-dose toxicity study (Study No. 38166).

Rat serum	Treatment and dose level	Time-point of serum generation
Group 1 (main study) (animals 1-10, 16-25)	Vehicle buffer control (PBS/300 mM sucrose)	Day 17
Group 1 (recovery cohort) (animals 11-15, 26-30)		Day 38

4.3 Test System

- Recombinant His-tagged SARS-CoV-2-S spike protein S1 domain coated in high-protein binding 96-well plate

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- Recombinant His-tagged SARS-CoV-2-S spike protein RBD sub-domain coated in high-protein binding 96-well plate
- HEK293T/17 (ATCC® CRL-11268™; for VSV/SARS-CoV-2-S pseudovirus generation)
- VERO 76 (ATCC® CRL-1587™; for VSV/SARS-CoV-2-S pseudovirus titration and pseudovirus neutralization testing)

4.4 Materials

Table 4: Materials

Product name	Application/specification	Article no.	Working dilution	Provider
96-well Microplate	Clear flat bottom TC-treated microplate, with lid, sterile	655160	N/A	Greiner Bio-One GmbH
96-well Microplate	Clear V bottom microplate, with lid, sterile	655180	N/A	Greiner Bio-One GmbH
96-well MaxiSorp plate	Clear Flat-Bottom Immuno Nonsterile 96-Well Plates for ELISA	439454	N/A	Thermo Fisher Scientific
50 mL tube	Conical bottom, PP, 30/115 MM, CELLSTAR®	227261	N/A	Greiner Bio-One GmbH
Cover films	ELISA	RATI6018410	N/A	VWR International GmbH
Eppendorf safe-lock tubes	0.5 mL/ 2.0 mL, Eppendorf Quality™	0030121023/ 0030120094	N/A	Eppendorf Vertrieb Deutschland GmbH
Pipette tips	ep Dualfilter T.I.P.S.®, PCR clean und sterile, 0.1–10 µL/2–100 µL/50–1000 µL/50–1250 µL/0.1–5 mL	0030077512/ 0030077547/ 0030077555/ 0030077792/ 0030077750/ 0030078616	N/A	Eppendorf Vertrieb Deutschland GmbH
Serological pipet	5 mL/10 mL/25 mL	606180 607180 760180	N/A	Greiner Bio-One GmbH
Reagent reservoir	25 mL, 100 mL	613-1179 613-1171	N/A	VWR International GmbH
Sodium Bicarbonate	ELISA, coating buffer	S5761	N/A	Sigma-Aldrich Chemie GmbH
Sodium Carbonate	ELISA, coating buffer	S7795	N/A	Sigma-Aldrich Chemie GmbH
Phosphate buffered saline (PBS), powdered	ELISA, PBS-T buffer	0780-10L	1x	VWR International GmbH
Tween 20	ELISA, PBS-T buffer	9127.1	n/a	Carl Roth GmbH & Co. KG
Casein Blocking Buffer 10x	ELISA	B6429-500 ml	1x	Sigma-Aldrich Chemie GmbH

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Product name	Application/specification	Article no.	Working dilution	Provider
TMB one ready to use-solution	ELISA	4380A	1x	Biotrend Chemiekalien GmbH
Sulphuric acid 25% EMSURE®	ELISA	1007161000	n/a	VWR International GmbH
Anti-Rabbit IgG (whole molecule) POX	ELISA	A0545-1ML	1:10000	Sigma-Aldrich
Mouse Anti-Rat IgG (H+L) HRP	ELISA	212-035-168	1:10000	Jackson ImmunoResearch
rat IgG-UNLB	ELISA	0108-01	Starting dilution 1:300	Southern Biotech
SARS-CoV-2 (2019-nCoV) Sp ke Antibody, Rabbit Mab	ELISA	40150-R007	1:500/ 1:1000	SinoBiological
Recombinant S protein NCP-CoV(2019-nCoV) Sp ke Protein (S1 Subunit, His Tag)	ELISA	40591-V08H	100 ng/ 100 µL	SinoBiological
Recombinant RBD protein 2019-nCoV Spike Protein (RBD, His Tag)	ELISA	40592-V08B	100 ng/ 100 µL	SinoBiological
Epoch Absorbance reader	ELISA	n/a	n/a	BioTek
Tecan Washer	ELISA	n/a	n/a	Tecan
Orbital shaker with heating function	ELISA	n/a	n/a	Heidolph
DMEM medium	High glucose, GlutaMAX™ Supplement, pyruvate	31966-047	N/A	Life Technologies GmbH
Fetal Bovine Serum	Non-USA origin, sterile-filtered	F7524	N/A	Sigma-Aldrich Chemie GmbH
DPBS	No calcium, no magnesium	14190-094	1 ×	Thermo Fisher Scientific
Penicillin-Streptomycin	10,000 U/mL	15140-122	33 U/mL	G bco
2 mL tube	CRYO.S, round bottom	122278	N/A	Greiner Bio-One GmbH
Dimethyl sulfoxide	For cell culture	A3672,0100	N/A	AppliChem GmbH
Lipofectamine® LTX & PLUS™ Reagent	Pseudovirus generation	15338-100	N/A	Life Technologies GmbH
VSV-ΔG-GFP Plasmid Expression Vector System	With set of Helper Plasmids (VSV-N, VSV-P, VSV-L, VSV-G); for VSV-ΔG-GFP generation	EH1004	N/A	Kerafast, Inc.

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Product name	Application/specification	Article no.	Working dilution	Provider
VSV-G antibody,	Mouse IgG2a kappa; clone 8G5F11	EB0010	0.5 µg/mL	Kerafast, Inc.
Filter	0.45 µm Acrodisc®, Supor®	514-4123	N/A	VWR International GmbH
Incubator	Heracell 150i	N/A	N/A	Thermo Fisher Scientific
Sterile safety cabinet	Hera Safe HS18	N/A	N/A	Thermo Fisher Scientific
Live-Cell Analysis System	IncuCyte S3	N/A	N/A	Essen Bioscience
Microplate shaker	Titramax 100	N/A	N/A	Heidolph Instruments GmbH
Water bath	TW8	N/A	N/A	Julabo GmbH

Table 5: Software

Product name	Application	Provider
Excel	Animal monitoring, raw data	Microsoft Corp.
GraphPad Prism 8	Analysis of ELISA and pVNT assay	Graphpad Software Inc.

4.5 Methods

4.5.1 ELISA

Serum samples were tested in 96-well plates for their S-specific antibody concentration based on SOP-030-112 (with minor modifications as described below). Briefly, for the time points 10 days (BNT162c1) or 17 days (BNT162a1, BNT162b1 and BNT162b2, see Section 4.1) after immunization, a screening analysis was performed.

1. Coat each well of a MaxiSorp plate with 100 ng recombinant protein (SARS-CoV2 S1 subunit or RBD) per well in 100 µL coating buffer (50 mM sodium carbonate buffer [1.696 g Na_2CO_3 + 2.856 g $NaHCO_3$ ad 1 L Aqua dest.], pH 9.6)
2. Cover plates and incubate at 4°C o/n.
3. Wash three times with 300 µL/well PBS-T (9 L Aqua dest. + 1 L 10x PBS + 1 mL Tween 20).
4. Block all wells with 250 µL/well blocking buffer (900 mL Aqua dest. + 100 mL 10x Casein Blocking Buffer)
5. Incubate at 37°C for 1 h on shaker.
6. Wash three times with 300 µL/well PBS-T.
7. Dilute primary antibodies (samples and positive control) according to schedule.
8. Incubate at 37°C for 1 h on shaker.
9. Wash three times with 300 µL/well PBS-T.

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10. Dilute the secondary antibodies according to calculations.
11. Incubate at 37°C for 45 min on shaker.
12. Wash three times with 300 µL/well PBS-T.
13. Add 100 µL/well TMB substrate.
14. Incubate 8 min at RT (clear->blue).
15. Stop the reaction with 100 µL 25% sulfuric acid (blue -> yellow).
16. Read on plate reader (450 nm, reference: 620 nm).

4.5.2 Production of SARS-CoV2-S pseudotyped VSV vector

Replication-deficient vesicular stomatitis virus (VSV) that lacks the genetic information for the VSV envelope glycoprotein VSV-G but contains an open-reading frame (ORF) for green fluorescent protein (GFP) was used for SARS-CoV-2-S pseudovirus generation. VSV pseudotypes were generated according to a published protocol (Hoffmann et al. 2020).

In brief, HEK293T/17 cells cultured in DMEM supplemented with 10% FBS were transfected with a pcDNA3.1-derived expression plasmid coding for the SARS-CoV-2 spike protein (GenBank ID: QHD43416.1) with shortened cytoplasmatic tail, i.e. pSARS-CoV-2-S-CΔ19, using Lipofectamine® LTX & PLUS™ Reagent following the manufacturer's instructions. The cytoplasmatic tail was truncated for the 19 C-terminal amino acids to facilitate a more efficient integration of SARS-CoV-2-S into VSV virions analogous to SARS-CoV-S pseudotyped VSV (Fukushi et al. 2005). At 24 h post transfection, cells were inoculated with VSV-G transcomplemented VSV-ΔG-GFP vector (Indiana strain, *de novo* generated by reverse genetics from plasmid (Lawson et al. 1995)) at a multiplicity of infection (MOI) of three and incubated for 2 h at 37°C and 5% CO2. Next, the inoculum was removed, cells were washed with phosphate-buffered saline (DPBS), and standard culture medium, which contained 0.5 µg/mL anti-VSV-G antibody, was added to neutralize residual input virus. Twenty-four hours after infection, VSV/SARS-CoV-2-S pseudovirus-containing supernatants were harvested, filtered and stored at -80 °C in aliquots until further use.

4.5.3 Titration of VSV/SARS-CoV2 pseudovirus

For titration of VSV/SARS CoV-2-S pseudovirus, Vero-76 cells were thawed according to SOP-030-041, diluted to 2.67×105 cells/mL in assay medium (DMEM/10% FBS) and seeded in 96-well flat-bottom plates at 4 × 10^4 cells per well. Cells were incubated for 4 to 6 hours at 37 °C and 7.5% CO2. Meanwhile, two-fold, eight-step serial dilutions were prepared in 96-well V-bottom plates beginning with undiluted pseudovirus supernatant. Vero-76 wells were inoculated with 50 µl of the diluted pseudovirus supernatant and incubated for 16 to 24 hours at 37 °C and 7.5% CO2. Each dilution was tested in duplicate wells. After the incubation, the cell culture plates were removed from the incubator, placed in an IncuCyte Live Cell Analysis system and equilibrated for 30 minutes prior to the analysis. Whole well scanning for brightfield and GFP fluorescence was performed using a 4× objective. The number of infected GFP-

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fluorescent cells per well was plotted as a function of pseudovirus supernatant dilution using GraphPad Prism v8. Data were fitted and the fitting equation used to calculate the amount of viral supernatant needed to obtain 144 infected cells/96-well (20% excess for virus neutralization test included; see Section 4.5.4).

4.5.4 Pseudovirus Neutralization Test

For analyzing the amount of nAbs in the serum samples, sera collected at 10 days (BNT162c1) or 17 days (BNT162a1, BNT162b1 and BNT162b2, see Section 4.1) after immunization were tested using the VSV/SARS-CoV-2-S pseudovirus neutralization test (pVNT). For the pVNT assay, Vero-76 cells were thawed according to SOP-030-041, diluted to 2.67×105 cells/mL in assay medium (DMEM/10% FBS) and seeded in 96-well flat-bottom plates at 4×10^4 cells per well. Cells were incubated for 4 to 6 hours at 37 °C and 7.5% CO2. Initial dilutions of rat serum samples were prepared by adding 10 µL of serum to 50 µL assay medium in a 96-well V-bottom plate. Seven additional dilutions were subsequently prepared in two-fold dilution steps, by iteratively transferring 30 µL of diluted sera to wells containing 30 µL assay medium. VSV/SARS-CoV-2 pseudovirus was thawed and diluted to obtain 120 infected cells/25 µL (4.8×10^3 infectious units [IU]/mL). 30 µL of diluted pseudovirus (corresponds to 144 infected cells; see Section 4.5.3) was added to the wells containing the serum dilution series. The pseudovirus/serum dilution mix was incubated for 5 minutes at room temperature (RT) on a Heidolph Titramax 100 microplate shaker at 750 rpm, and additional 5 min at RT without agitation. The pseudovirus/serum dilution mix was then added to the seeded Vero-76 cells (50 µL mix per well, MOI: 0.003), followed by incubation for 16 to 24 hours at 37 °C and 7.5% CO_2. Each dilution of serum samples was tested in duplicate wells. Vero-76 cells incubated with pseudovirus in the absence of rat sera were used as positive controls. Vero-76 cells incubated without pseudovirus were used as negative controls. After the incubation, the cell culture plates were removed from the incubator, placed in an IncuCyte Live Cell Analysis system and equilibrated for 30 minutes prior to the analysis. Whole well scanning for brightfield and GFP fluorescence was performed using a 4× objective. To calculate the neutralizing titer, infected GFP-positive cell number per well was compared with the no-serum pseudovirus positive control. Mean values of the no-serum pseudovirus positive control multiplied by 0.5 represents the pseudovirus neutralization 50% (pVN50); mean values of the no-serum pseudovirus positive control multiplied by 0.1 represents the pseudovirus neutralization 90%. Serum samples with mean values below this cut-off exhibit >50% or >90% virus neutralization activity, respectively.

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5 RESULTS

The exposure of rats to the four different BNT162 vaccine candidates was evaluated via SARS-CoV-2 spike protein specific antibody responses in an accessory study to the REPEAT-DOSE TOXICITY STUDY OF THREE LNP-FORMULATED RNA PLATFORMS ENCODING FOR VIRAL PROTEINS BY REPEATED INTRAMUSCULAR ADMINISTRATION TO WISTAR HAN RATS (b) (4) Study No. 38166). In this toxicity study rats were injected intramuscularly with different dose levels of BNT162a1, BNT162b1 or a single dose level of BNT162b2 or BNT162c1. Table 6 summarizes the treatment groups.

Table 6: Overview of treatment groups in LPT study no. 38166

Treatment group	Dose level / product	RNA platform	Antigen	Translated Protein
1			Vehicle Buffer Control	
2	30 µg BNT162a1	uRNA	V5	Secreted RBD variant with a C-terminal trimerization domain
3	10 µg BNT162a1			
4	30 µg BNT162b1	modRNA	V5	Secreted RBD variant with a C-terminal trimerization domain
5	100 µg BNT162b1			
6	30 µg BNT162c1	saRNA	V5	Secreted RBD variant with a C-terminal trimerization domain
7	100 µg BNT162b2	modRNA	V8	Membrane tethered, mutated full-length S protein

Whereas uRNA and modRNA based vaccines were administered three times one week apart (days 1, 8, 15), the saRNA based vaccine was administered only twice with one week apart (days 1, 8). The capacity of the RNA-encoded antigens to induce antibody responses was studied using ELISA and pVNT assay.

5.1 ELISA

Induced antibody responses directed against the SARS-CoV-2 spike protein S1 domain and RBD sub-domain were assessed at day 10 after two immunization rounds (BNT162c1) or day 17 after three rounds of immunization (BNT162a1, BNT162b1, and BNT162b2; Table 6), as well as from the treated recovery cohorts at day 31 (BNT162c1) or at day 38 (BNT162a1, BNT162b1, and BNT162b2). Due to the unknown strength of the elicited immune response, different dilutions of rat serum ranging from 1:100 to 1:24,300 were tested as part of an ELISA screening analysis.

Treatment of rats with each of the BNT162 vaccine candidates resulted in the formation of antibodies of the IgG isotype against the S1 domain as well as the RBD sub-domain of the SARS-CoV-2 spike protein, while these antibodies were not detected in samples

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from vehicle buffer control treated animals (Figure 2, Figure 3, Figure 4 and Figure 5). The analysis showed a weak antibody immune response for BNT162c1 treated animals at day 10 and day 31, a moderate antibody immune response for BNT162a1 treated animals at day 17 and day 38, and a strong antibody immune response for both modRNA based vaccines, BNT162b1 and BNT162b2, at day 17 and day 38, irrespective of the vaccine antigen used. Whereas for the BNT162b1 cohort the magnitude of immune activation was dose-dependent, the low-dose (10 µg/animal) BNT162a1 treated animals displayed a slightly more pronounced antibody immune response with higher titers of antigen-specific IgG in serum compared to the high-dose (30 µg/animal) treated cohort.

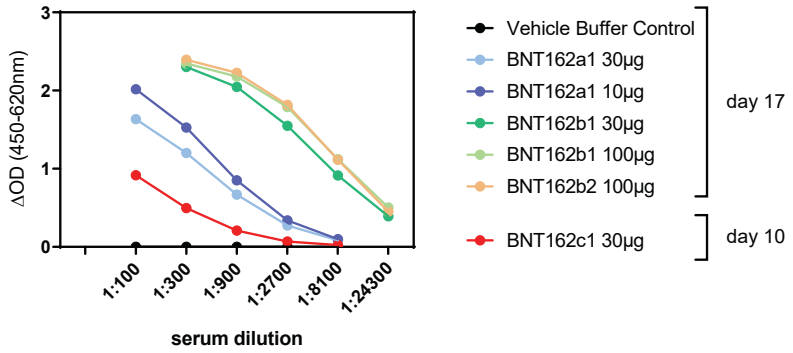


Figure 2: ELISA screening analysis of main study cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein S1 domain

ELISA was performed using serum samples collected on day 10 after two immunizations (prime/boost on days 1 and 8) with BNT162c1, or on day 17 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the S1 protein. Group mean ΔOD values of n=20 mice/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

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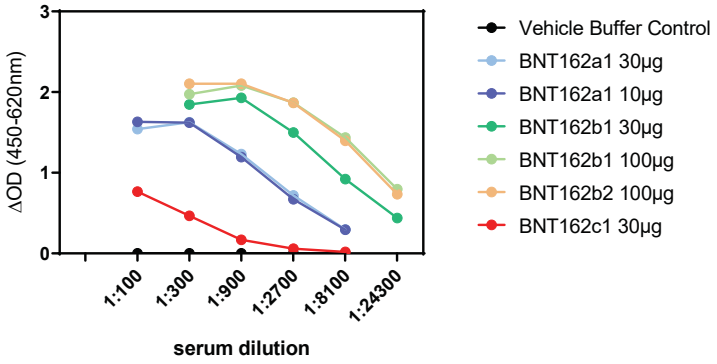


Figure 3: ELISA screening analysis of recovery cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein S1 domain

ELISA was performed using serum samples collected on day 31 after two immunizations (prime/boost on days 1 and 8) with BNT162c1, or on day 38 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the S1 protein. Group mean ΔOD values of n=20 mice/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

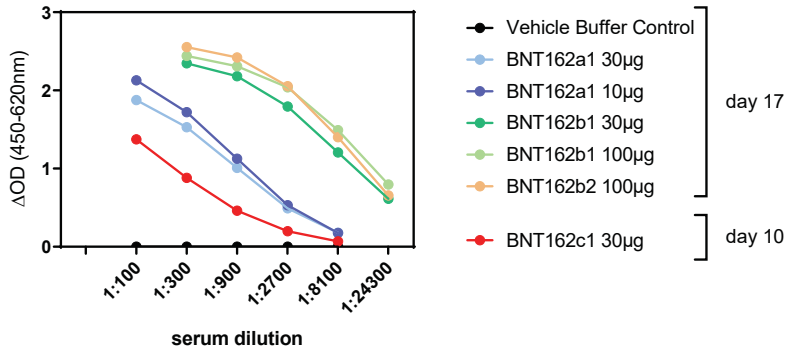


Figure 4: ELISA screening analysis of main study cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein RBD domain

ELISA was performed using serum samples collected on day 10 after two immuniza ions (prime/boost on days 1 and 8) with BNT162c1, or on day 17 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the RBD domain. Group mean ΔOD values of n=20 rats/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

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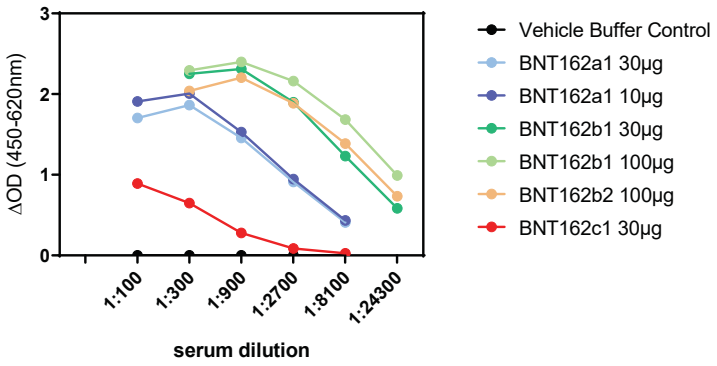


Figure 5: ELISA screening analysis of recovery cohort sera to detect antibody responses directed against the recombinant SARS-CoV-2 spike protein RBD domain

ELISA was performed using serum samples collected on day 31 after two immuniza ions (prime/boost on days 1 and 8) with BNT162c1, or on day 38 after three administrations (prime/boost on days 1/8/15) of BNT162a1, BNT162b1, or BNT162b2 to analyze elicited antibody responses. The serum samples were tested against the RBD domain. Group mean ΔOD values of n=20 rats/group are shown by dots across serum dilutions ranging from 1:100 to 1:24,300.

5.2 Pseudovirus-based Neutralization Test

To functionally characterize the elicited SARS-CoV-2 spike protein specific antibody response in rats, the neutralizing capacity of sera was assessed employing a VSV/SARS-CoV-2-S pseudovirus system in conjunction with Vero 76 cells as target. Vero 76 cell express endogenous angiotensin-converting enzyme 2 (ACE2), the identified entry receptor for SARS-CoV-2 (Hoffmann et al. 2020). Sera of ten representative animals per cohort and time-point (generated from n=5 male and n=5 female rats) were analyzed.

Treatment of rats with each of the BNT162 vaccine candidates resulted in the formation of neutralizing antibodies protecting Vero 76 cells against pseudovirus infection (titer resulting in 50% pseudovirus neutralization in Figure 6 and Figure 7; titer resulting in 90% pseudovirus neutralization in Figure 8 and Figure 9). In contrast, no neutralizing activity was associated with serum samples generated from vehicle buffer control treated animals. Neutralizing antibody titers in vaccinated animals increased over time with the recorded neutralizing activity being consistent with the ELISA data shown in Section 5.1. Whereas sera from BNT162c1 treated animals display weak neutralizing activity both at days 10 and 31, sera from BNT162a1 treated animals display moderate neutralizing activity at day 17 that is significantly augmented at day 38. The strongest pseudovirus neutralization effect is mediated by sera generated from BNT162b1- and BNT162b2-treated rats. In case of both modRNA-based vaccines, BNT162b1 and

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BNT162b2, neutralizing antibody titers resulting in 50% pseudovirus neutralization exceeded the upper limit of quantification (ULOQ) of a reciprocal titer of 1536 in more than 8 out of ten animals at day 38.

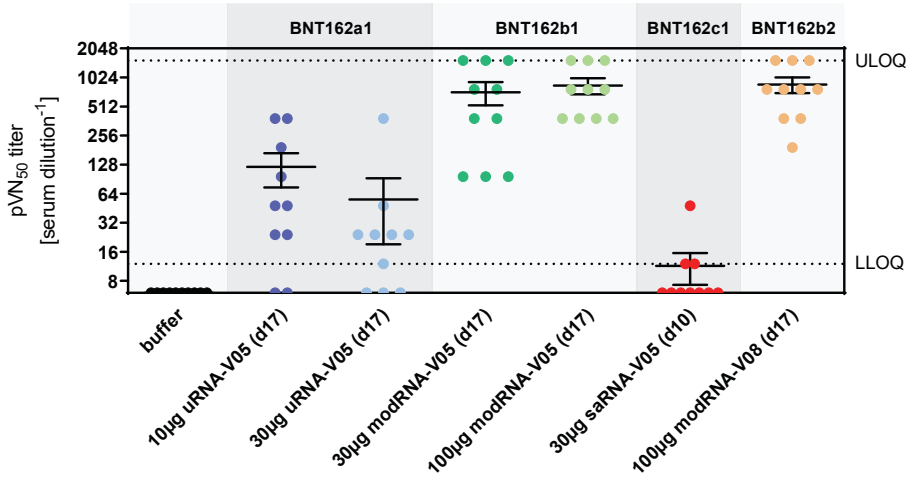


Figure 6: Pseudovirus neutralization activity of main study cohort sera plotted as pVN_{50} titer

Serum samples were collected on day 10 (BNT162c1, red dots) or day 17 (all other cohorts) after first immunization of the main study animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 50% pseudovirus neutralization (pVN_{50}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

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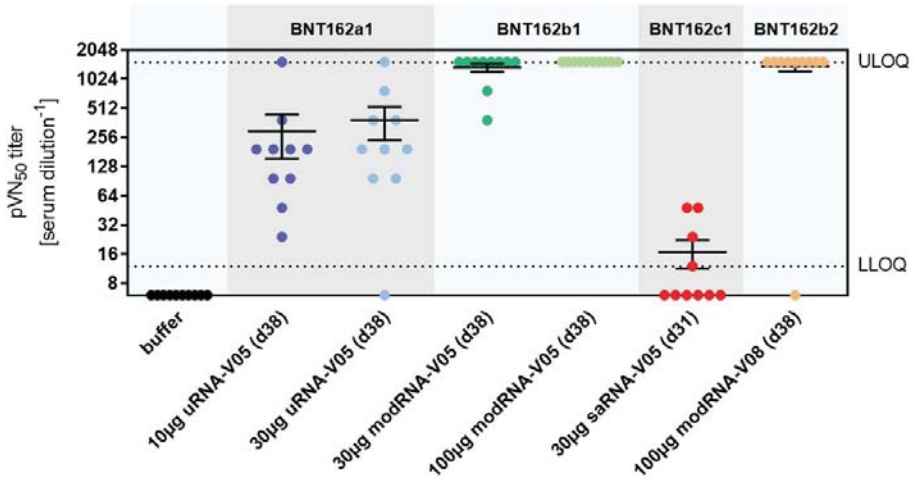


Figure 7: Pseudovirus neutralization activity of recovery cohort sera plotted as pVN_{50} titer

Serum samples were collected on day 31 (BNT162c1, red dots) or day 38 (all other cohorts) after first immunization of the recovery cohort animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 50% pseudovirus neutralization (pVN_{50}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

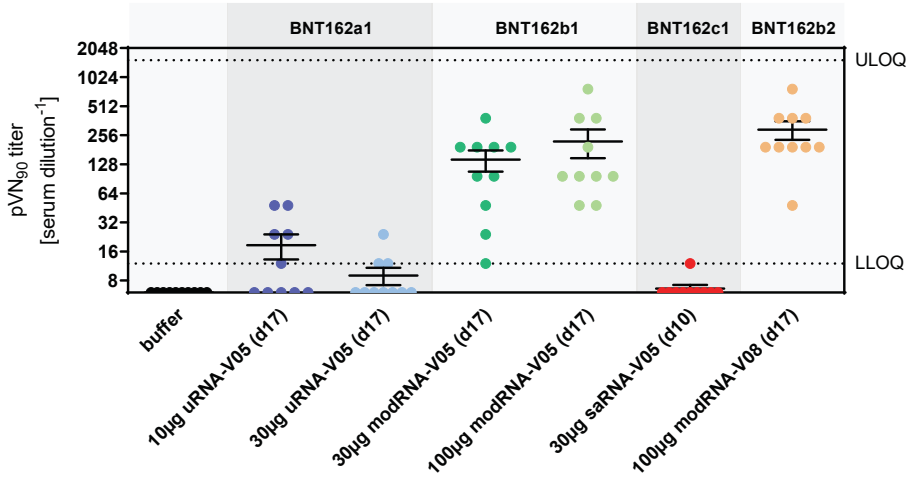


Figure 8: Pseudovirus neutralization activity of main study cohort sera plotted as pVN_{90}

Serum samples were collected on day 10 (BNT162c1, red dots) or day 17 (all other cohorts) after first immunization of the main study animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 90% pseudovirus neutralization (pVN_{90}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

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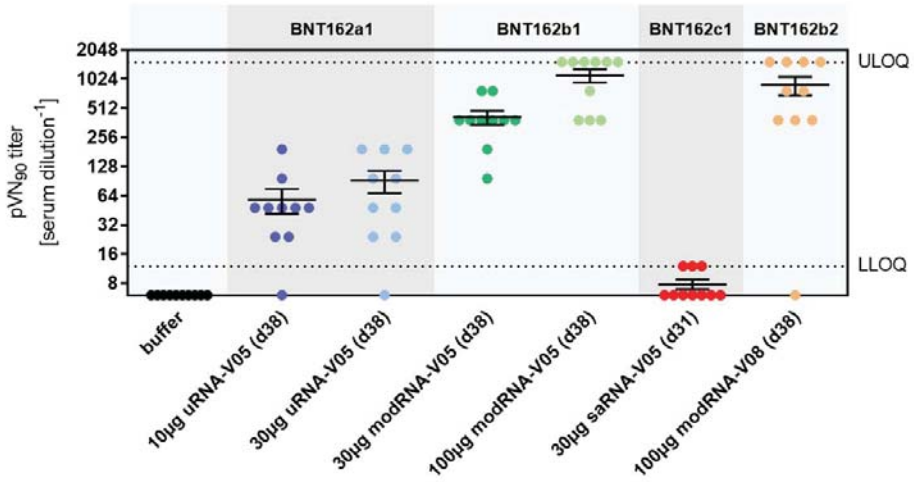


Figure 9: Pseudovirus neutralization activity of recovery cohort sera plotted as pVN_{90}

Serum samples were collected on day 31 (BNT162c1, red dots) or day 38 (all other cohorts) after first immunization of the recovery cohort animals and titers of virus-neutralizing antibodies were determined by pseudovirus-based neutralization test (pVNT). Individual VNT titers resulting in 90% pseudovirus neutralization (pVN_{90}) are shown by dots; group mean values are indicated by horizontal bars (±SEM, standard error of the mean).

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6 CONCLUSION

The available data demonstrates that all BNT162 vaccine candidates elicited a SARS-CoV-2 spike protein specific antibody response directed against the S1 domain and the RBD sub-domain. Antibody responses detected via ELISA directly translated into neutralizing activity as seen in the VSV/SARS-CoV2-S pseudovirus neutralization test with BNT162 vaccines showing higher antigen-specific antibody titers also displaying more pronounced virus neutralization effect. A comparison of the three RNA platforms with regard to their immunogenicity in rats may not be fully predictive for how they may perform relative to each other in human due to species-specific differences in immunity mechanisms.

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7 DOCUMENT HISTORY

First version / no change.

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9 APPENDIX

Appendix 1: pVNT raw data

Table 7: Pseudovirus neutralization activity of sera generated from male rats in group 1

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		1	2	3	4	5	Virus control	Cell control	VN50
1:12	A	98,6	108,5	112,0	93,2	105,3	100	0	50
1:24	B	90,4	81,9	91,1	96,8	100,2			
1:48	C	97,9	105,3	99,1	100,3	97,3			
1:96	D	115,9	95,9	86,6	92,8	91,1			
1:192	E	95,3	99,5	82,0	70,8	78,2			
1:384	F	98,3	63,2	69,4	33,7	31,8			
1:768	G	86,9	56,3	54,5	55,9	40,6			
1:1536	H	84,0	81,2	76,3	60,8	61,9			

Table 8: Pseudovirus neutralization activity of sera generated from female rats in group 1

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		16	17	18	19	20	Virus control	Cell control	VN50
1:12	A	113,7	138,3	134,2	99,3	104,8	100	0	50
1:24	B	112,1	108,5	113,6	97,8	111,1			
1:48	C	125,4	116,5	118,4	113,6	111,6			
1:96	D	122,3	67,9	72,3	67,1	91,5			
1:192	E	111,8	66,5	74,2	72,5	63,2			
1:384	F	119,7	77,2	46,3	53,6	54,6			
1:768	G	123,2	97,3	54,6	70,8	66,9			
1:1536	H	97,3	75,1	84,3	77,5	56,4			

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Table 9: Pseudovirus neutralization activity of sera generated from male rats in group 2

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		31	32	33	34	35	Virus control	Cell control	VN50
1:12	A	90,8	10,1	8,5	100,0	18,1	100	0	50
1:24	B	89,1	38,4	31,9	119,3	39,9			
1:48	C	112,8	76,5	64,8	123,0	64,2			
1:96	D	118,6	75,9	61,1	104,4	62,3			
1:192	E	97,3	61,1	39,4	74,2	65,7			
1:384	F	99,3	62,6	46,8	77,1	64,8			
1:768	G	111,1	104,6	100,3	69,3	86,7			
1:1536	H	110,8	102,6	82,9	72,9	65,7			

Table 10: Pseudovirus neutralization activity of sera generated from female rats in group 2

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		46	47	48	49	50	Virus control	Cell control	VN50
1:12	A	28,7	99,8	9,9	15,3	0,8	100	0	50
1:24	B	53,8	122,7	37,7	34,1	1,5			
1:48	C	75,3	133,1	63,3	50,0	14,4			
1:96	D	82,8	126,1	55,3	62,6	26,4			
1:192	E	110,2	131,2	72,1	86,5	39,0			
1:384	F	88,0	66,3	45,4	57,4	35,4			
1:768	G	114,0	97,8	86,3	88,3	60,0			
1:1536	H	85,4	74,7	78,4	78,5	37,9			

Table 11: Pseudovirus neutralization activity of sera generated from male rats in group 3

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		61	62	63	64	65	Virus control	Cell control	VN50
1:12	A	20,3	72,8	6,0	4,4	14,9	100	0	50
1:24	B	43,2	84,4	31,3	8,1	41,3			
1:48	C	58,9	95,6	47,5	19,9	60,0			
1:96	D	78,6	99,6	73,0	33,6	83,4			
1:192	E	84,6	106,9	96,9	53,9	92,1			
1:384	F	95,9	109,3	87,1	62,9	95,2			
1:768	G	84,2	91,5	93,4	60,6	95,2			
1:1536	H	91,1	94,0	90,3	85,9	96,1			

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Table 12: Pseudovirus neutralization activity of sera generated from female rats in group 3

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		76	77	78	79	80	Virus control	Cell control	VN50
1:12	A	1,7	10,0	63,3	0,0	0,4	100	0	50
1:24	B	5,8	25,1	86,7	1,4	2,3			
1:48	C	12,5	44,6	101,0	6,0	6,2			
1:96	D	24,7	58,1	103,5	12,2	20,5			
1:192	E	36,1	76,1	96,1	24,9	34,2			
1:384	F	58,5	90,9	99,0	48,5	43,1			
1:768	G	72,6	91,7	98,8	51,2	62,7			
1:1536	H	76,3	98,5	90,3	65,6	64,5			

Table 13: Pseudovirus neutralization activity of sera generated from male rats in group 4

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		91	92	93	94	95	Virus control	Cell control	VN50
1:12	A	0,0	0,0	2,9	0,6	1,0	100	0	50
1:24	B	0,0	0,3	5,2	1,0	1,6			
1:48	C	1,0	0,6	21,7	0,3	1,6			
1:96	D	3,2	1,9	22,7	3,6	5,2			
1:192	E	20,7	2,3	60,2	4,9	17,2			
1:384	F	45,6	11,3	69,3	16,8	31,1			
1:768	G	72,5	27,2	95,5	31,4	65,7			
1:1536	H	112,3	35,6	134,6	55,3	99,4			

Table 14: Pseudovirus neutralization activity of sera generated from female rats in group 4

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		106	107	108	109	110	Virus control	Cell control	VN50
1:12	A	0,7	0,3	2,4	0,0	0,7	100	0	50
1:24	B	2,9	0,1	12,7	0,1	0,1			
1:48	C	7,9	0,4	24,4	0,4	0,8			
1:96	D	28,6	1,0	39,2	0,7	1,6			
1:192	E	50,7	6,0	61,5	2,4	6,9			
1:384	F	66,8	16,9	63,0	7,1	15,8			
1:768	G	86,1	34,8	75,4	16,7	31,6			
1:1536	H	79,5	55,2	74,6	31,2	42,3			

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Table 15: Pseudovirus neutralization activity of sera generated from male rats in group 5

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		121	122	123	124	125	Virus control	Cell control	VN50
1:12	A	0,0	0,2	0,7	0,2	0,7	100	0	50
1:24	B	0,9	0,0	0,0	0,0	0,9			
1:48	C	5,7	0,9	0,0	0,9	1,5			
1:96	D	16,1	4,6	2,0	1,1	9,6			
1:192	E	29,6	13,5	10,4	5,2	21,3			
1:384	F	47,8	23,9	19,6	8,0	37,6			
1:768	G	66,5	40,2	40,2	25,9	54,1			
1:1536	H	76,7	52,0	67,8	40,9	65,9			

Table 16: Pseudovirus neutralization activity of sera generated from female rats in group 5

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		136	137	138	139	140	Virus control	Cell control	VN50
1:12	A	0,0	0,2	0,0	0,0	0,4	100	0	50
1:24	B	0,4	0,0	0,9	0,0	0,0			
1:48	C	0,4	0,4	2,4	0,2	0,0			
1:96	D	4,4	2,9	11,0	0,2	0,0			
1:192	E	17,6	6,4	25,3	3,3	0,4			
1:384	F	19,6	12,3	28,6	4,2	2,0			
1:768	G	61,5	33,7	71,1	20,0	8,6			
1:1536	H	75,1	51,3	85,0	37,7	26,2			

Table 17: Pseudovirus neutralization activity of sera generated from male rats in group 6

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		151	152	153	154	155	Virus control	Cell control	VN50
1:12	A	27,4	105,2	62,6	108,1	122,0	100	0	50
1:24	B	54,0	106,8	67,8	108,1	124,8			
1:48	C	80,5	111,9	75,2	109,1	106,6			
1:96	D	98,4	107,1	81,0	115,5	99,7			
1:192	E	91,5	113,3	73,7	92,9	115,5			
1:384	F	87,7	104,3	94,0	100,1	94,3			
1:768	G	98,9	91,0	88,7	95,7	97,0			
1:1536	H	93,2	85,6	90,9	95,1	90,5			

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Table 18: Pseudovirus neutralization activity of sera generated from female rats in group 6

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		166	167	168	169	170	Virus control	Cell control	VN50
1:12	A	143,0	101,3	134,0	4,0	31,0	100	0	50
1:24	B	90,6	109,4	104,8	14,6	61,7			
1:48	C	89,5	90,8	101,5	31,7	80,6			
1:96	D	90,7	89,6	106,1	52,1	93,8			
1:192	E	90,3	86,8	93,5	66,8	99,5			
1:384	F	96,0	104,4	101,0	77,5	92,4			
1:768	G	89,7	97,3	101,2	84,5	101,2			
1:1536	H	89,0	91,5	94,9	87,0	89,8			

Table 19: Pseudovirus neutralization activity of sera generated from male rats in group 7

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		181	182	183	184	185	Virus control	Cell control	VN50
1:12	A	0,2	0,0	0,0	0,0	0,0	100	0	50
1:24	B	0,2	1,2	0,7	0,0	0,0			
1:48	C	2,1	0,2	0,7	0,5	1,2			
1:96	D	11,5	0,0	0,9	1,2	0,2			
1:192	E	29,7	3,3	5,9	9,9	2,1			
1:384	F	63,6	16,3	22,9	23,6	10,8			
1:768	G	101,1	46,2	54,4	57,7	37,5			
1:1536	H	131,2	88,8	91,4	91,2	77,3			

Table 20: Pseudovirus neutralization activity of sera generated from female rats in group 7

Neutralization activity of each serum at a given serum dilution is calculated as % infectivity compared to the virus control. Green shaded boxes indicate wells with virus neutralization activity >50%; red shaded boxes indicate wells with virus neutralization activity >90%.

Serum dilution		196	197	198	199	200	Virus control	Cell control	VN50
1:12	A	0,0	0,0	0,2	0,0	0,0	100	0	50
1:24	B	0,0	0,2	0,2	0,0	0,0			
1:48	C	0,0	0,4	0,9	0,0	0,0			
1:96	D	0,0	0,0	1,3	1,1	0,0			
1:192	E	0,0	0,2	4,9	0,7	1,8			
1:384	F	2,9	5,3	15,5	4,0	9,9			
1:768	G	9,9	16,1	44,4	12,2	20,8			
1:1536	H	41,8	38,7	85,3	22,1	58,6			

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